Strengthening medical abortion in South Africa

By

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DECLARATION

I, Deborah Constant, hereby declare that the work on which this thesis is based is original research and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Deborah Ann Constant
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ABSTRACT

Access to safe, legal abortion services is an important public health measure to address morbidity and mortality from unsafe abortion. To expand access and strengthen medical abortion provision in South Africa, evidence is needed on the safety, effectiveness, feasibility and acceptability of task sharing strategies and the implementation of evidence-based regimens.

This research aims to: (a) evaluate the safety and acceptability of task sharing gestational age estimation for women seeking abortion, (b) determine the effectiveness and acceptability of text messaging on mobile phones to support women self-managing medical abortion, (c) evaluate the feasibility, safety and acceptability of self-assessment of medical abortion completion using mobile phones alone or in combination with a low-sensitivity pregnancy test, and (d) document clinical outcomes and women's experiences following the introduction of mifepristone into second trimester medical abortion services.

Published or submitted papers included in this thesis are from four prospective studies evaluating interventions and interviewing women and health care workers in South African public sector and non-governmental clinics between 2011 and 2015. The first paper establishes that last menstrual period is sufficiently accurate to estimate gestational age in selected women (97%) and has potential to be task shared with community health workers or women themselves. The second paper reports reduced anxiety ($p=0.013$) and better preparedness ($p=0.016$) for self-managing abortion symptoms among women receiving automated text messages (compared to those receiving standard care). The third and fourth papers show that mobile phones are a feasible modality for self-assessment for most women (86%), but that clinical history needs to be combined with an appropriate pregnancy test to detect incomplete or failed procedures. Self-assessment using a low-sensitivity pregnancy test is preferred by most women (98%) to in-clinic follow-up, and providing a guided demonstration on the use of a low-sensitivity pregnancy test does not significantly impact on the accuracy of self-assessed abortion outcome compared to simple verbal instructions (88% vs. 85% accuracy; $p=0.449$). The fifth paper documents successful self-administration of mifepristone, a higher 24-hour abortion rate (93% vs 77%; $p<0.001$), and

greater acceptability following the introduction of mifepristone into second trimester abortion care, compared to historic cohorts receiving misoprostol only.

The thesis concludes that supported self-management and task sharing can strengthen medical abortion provision in South Africa. Research evaluating task sharing of medical abortion care has potential to inform similar approaches for other health care services.

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PREFACE

This thesis includes published papers, manuscripts submitted for publication, and manuscripts prepared for submission as per general provision 6.7 in the General Rules for the Degree of Doctor of Philosophy (PhD) of the University of Cape Town, and with the approval in July 2016 of the University Doctoral Degrees Board. The analyses and drafting of all papers was conducted by the candidate during the period of doctoral degree registration.

The following five papers and manuscripts are included as part of the thesis.

1. Accuracy of gestational age estimation from last menstrual period among women seeking abortion in South Africa, with a view to task sharing: a mixed methods study. *Submitted for publication to Reproductive Health (August 2016)*.

2. Mobile phone messages to provide support to women during the home phase of medical abortion in South Africa: a randomised controlled trial. *Contraception 2014; Sep;90(3)226-33.*

3. Self-assessment of medical abortion completion using a text questionnaire on mobile phones among South African women. *Reproductive Health Matters 2015;22(44) Suppl 1:83-93.*

4. Self-assessment of medical abortion outcome in South Africa: A non-inferiority, randomized controlled trial. *Prepared for submission to Obstetrics and Gynecology (August 2016).*

5. Clinical outcomes and women's experiences before and after the introduction of mifepristone into second-trimester medical abortion services in South Africa. *PLoS One 2016;Sep 1;11(9):e0161843*

The contribution of the candidate is outlined in the introduction to each of the papers

(Chapters 3, 4, 5, 6 and 7). The candidate was the lead author for all the papers and manuscripts. She was responsible for study design in Studies 2 and 3, and contributed to study design in Studies 1 and 4. The candidate prepared all the data sets for analysis, conducted all the analyses and drafted all versions of the manuscripts under the supervision of her doctoral advisors. All co-authors critically reviewed and approved the submitted manuscripts and the candidate was responsible for incorporating co-author's comments as appropriate.

LIST OF ACRONYMS AND ABBREVIATIONS

ANC	African National Congress
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
CHW	Community health worker
CL	Checklist
CI	Confidence interval
CTOPA	Choice on Termination of Pregnancy Act
D&E	Dilation and evacuation (abortion technique)
DOH	Department of Health
EDL	Essential Drug List
FDA	Food and Drug Administration
FU	Follow-up
GA	Gestational age
hCG	Human chorionic gonadotrophin
HCP	Health-care professional
HCW	Health-care worker
HIV	Human immunodeficiency virus
HSUPT	High-sensitivity urine pregnancy test
HR	Hazard ratio
IDI	In-depth interview
ICPD	International Conference on Population and Development
ITT	Intention to treat
KZN	KwaZulu-Natal
LARC	Long-acting, reversible contraception
LMIC	Low- and middle-income countries
LMP	Last menstrual period
LSUPT	Low-sensitivity urine pregnancy test
LTF	Loss to follow-up
MA	Medical abortion
MCC	Medicines Control Council
MDGs	Millennium Development Goals
MLUPT	Multi-level urine pregnancy test
MNCH	Maternal, new-born and child health
MVA	Manual vacuum aspiration (abortion technique)
NDOH	National Department of Health
NGO	Non-governmental organization
NPV	Negative predictive value
OBGYN	Obstetrician gynecologist

O/C	Outcome
OR	Odds ratio
PE	Physical examination
PoA	Plan of action
PPV	Positive predictive value
PTSD	Post-traumatic stress disorder
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomized controlled trial
SDGs	Sustainable Development Goals
SQUPT	Semi-quantitative urine pregnancy test
SMS	Short message service
SRH	Sexual and reproductive health
SRHR	Sexual and reproductive health and rights
TOP	Termination of pregnancy (abortion)
UK	United Kingdom
UN	United Nations
UNFPA	United Nations Population Fund
US	United States
U/S	Ultrasound
USSD	Unstructured supplementary service data
WCDOH	Western Cape Department of Health
WCW	World Conference on Women
WHO	World Health Organization

GLOSSARY OF TERMS

Cadres: Levels or categories of providers of abortion care, for example community health worker. Woman seeking or undergoing abortion are considered belong to a separate cadre.

Community Health Worker: Any health worker who performs functions related to health-care delivery; was trained in some way in the context of the intervention; but has received no formal professional or para-professional certificate or tertiary education degree.

High sensitivity urine pregnancy test: A pregnancy test that detects human chorionic gonadotrophin in a urine specimen with detection thresholds of 10mIU/mL to 100 mIU/mL.

Home abortion: Medical abortion when the misoprostol dose is self-administered at home.

Low-sensitivity urine pregnancy test: A pregnancy test that detects human chorionic gonadotrophin in a urine specimen with detection thresholds of 1000 or 2000mIU/mL.

mHealth: The delivery of health related services via mobile communications technology.

Mifepristone: Also known as RU 486, mifepristone is a synthetic progesterone antagonist that binds with high affinity to progesterone receptors. It activates and increases the sensitivity of the myometrium to prostaglandins. Mifepristone also softens and dilates the cervix.

Misoprostol: Misoprostol (brand name Cytotec) is a synthetic prostaglandin E1 analogue that was first approved for the prevention and treatment of gastric ulcers in 1985. Misoprostol is also widely used for a variety of different obstetric and gynecological indications. It causes strong myometrial contractions leading to expulsion of tissue from the pregnant uterus, as well as softening and dilation of the cervix.

Manual Vacuum Aspiration: An abortion procedure that uses a flexible plastic cannula, which is connected to a manual aspiration syringe with a locking valve to perform a uterine evacuation.

Nurse (registered): A person who has been legally authorized to practice after examination by an official board of nurse examiners or similar regulatory authority.

Self-management: Management of tasks and subtasks of the medical abortion process by women themselves, outside of a health care facility.

Self-administration: a specific aspect of self-management, the act of taking the medication (mifepristone, misoprostol, or both) outside of a health care facility without clinical supervision.

Self-assessment: Assessment by a woman without provider assistance that 1) she is eligible for medical abortion or 2) that her abortion process is complete and that no further intervention is required.

Short message service: A text messaging service component of mobile phone communication systems. It uses standardized communications protocols to allow mobile phone devices to exchange short text messages.

Semi-quantitative urine pregnancy test: A pregnancy test that detects human chorionic gonadotrophin in a urine specimen reading sequential ranges: ≥25 mIU/mL, ≥100 mIU/mL, ≥500 mIU/mL, ≥2,000 mIU/mL, and ≥10,000 mIU/mL.

Task sharing: Usual providers retain the task, but involve or expand to other cadres.

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Chapter 1 Introduction

1.1 Background

Access to safe abortion is a reproductive right and a public health measure necessary to reduce the burden of mortality and morbidity from unsafe abortion. However, despite being a relatively common experience for women, abortion is a highly contentious issue, and this can result in barriers to access and denial of care (1-5).

Reproductive rights were increasingly recognized over the latter half of the 20th century through numbers of international treatises and declarations, with further gains made in the 21st century, most recently noted in the United Nations (UN) General Comment No 22 (4 March, 2016) (6-13). The 2016 UN General Comment reinforced the right of access to safe abortion as integral to the right to heath and linked to human rights. It further emphasized that neither ideology nor lack of willing health-care workers (HCWs) should result in denial of care in public or in private health care facilities (13).

Currently more than 70% of the world's population live in countries that permit abortion on a number of grounds, or without restriction. The emerging recognition of reproductive rights underpinned the liberalization of abortion laws in many countries, marking an intent to address the public health issue of unsafe abortion. However, compared to developed countries, where in most cases abortion is legal on broad grounds, the legal status of abortion in developing countries is variable. Abortion remains highly restricted in numbers of countries in North and sub-Saharan Africa, in South and Central America, in the Middle East and in South and South-East Asia, as well as Ireland, Poland and Malta (14).

Access to safe, legal abortion services is needed to address the mortality from unsafe abortion, estimated at 22,300 in developing regions for 2014, as well as the associated morbidity which is prevalent in developing countries where abortion is legal but access is limited (15, 16). In such settings, barriers that impede access to services can lead women to seek care from unsafe and illegal abortion providers (3, 15, 17). In settings where abortion is legal, the most common barrier to access is a scarcity of trained and willing providers (1, 4, 18). Access is further compromised by scarce facilities being concentrated mainly in urban

centers, over medicalization of procedures, lack of information and support systems for women especially in poorer and hard to reach areas, as well as other social factors. Structural improvements that can address some of these challenges include more effective referral pathways, a presence of trained healthcare workers in remote areas, and streamlining of services (19). However, it is anticipated that shortages of health care professionals (HCPs), and abortion providers in particular, will worsen in future years, and low-and middle-income countries (LMICs) are expected to be most affected by this (18, 20).

In South Africa the shortage of skilled providers is dire, which has major implications for sustainability of the current model of abortion service delivery (4, 21). To address this growing problem in the field of abortion care, the World Health Organization (WHO) has proposed task sharing specific components of abortion care among other cadres of the health workforce, such as community health workers as well as self-management, where published evidence indicates this is feasible, safe and acceptable (18). Supporting task sharing in abortion care in ways that that are suited to the South African context could significantly alleviate the pressure on the limited pool of providers, decentralize abortion care, streamline service provision and ultimately expand safe abortion access.

1.2 The South African context: abortion policies and service provision

The Choice on Termination of Pregnancy Act (CTOPA) of 1996 gives women access to safe and legal abortion on request up to a gestational age (GA) of 12 weeks. In the second trimester of pregnancy, 12 weeks 1 day to 20 weeks GA, an abortion may be performed in cases of rape, incest, socioeconomic hardship or health risk to the woman or fetus, and can only be performed by a registered medical doctor (22). The Act was considered liberal and progressive, but was contentious, and challenges and barriers in implementation have ensued which continue to hinder access to broad based services. Although numbers of abortions performed annually since the implementation of the CTOPA have increased some three and a half-fold (1997: 26,455; 2013: 90,160; 2014: 89,126 abortions performed) (23), the recent published literature from South Africa emphasizes that access remains very uneven and inadequate (24-26).

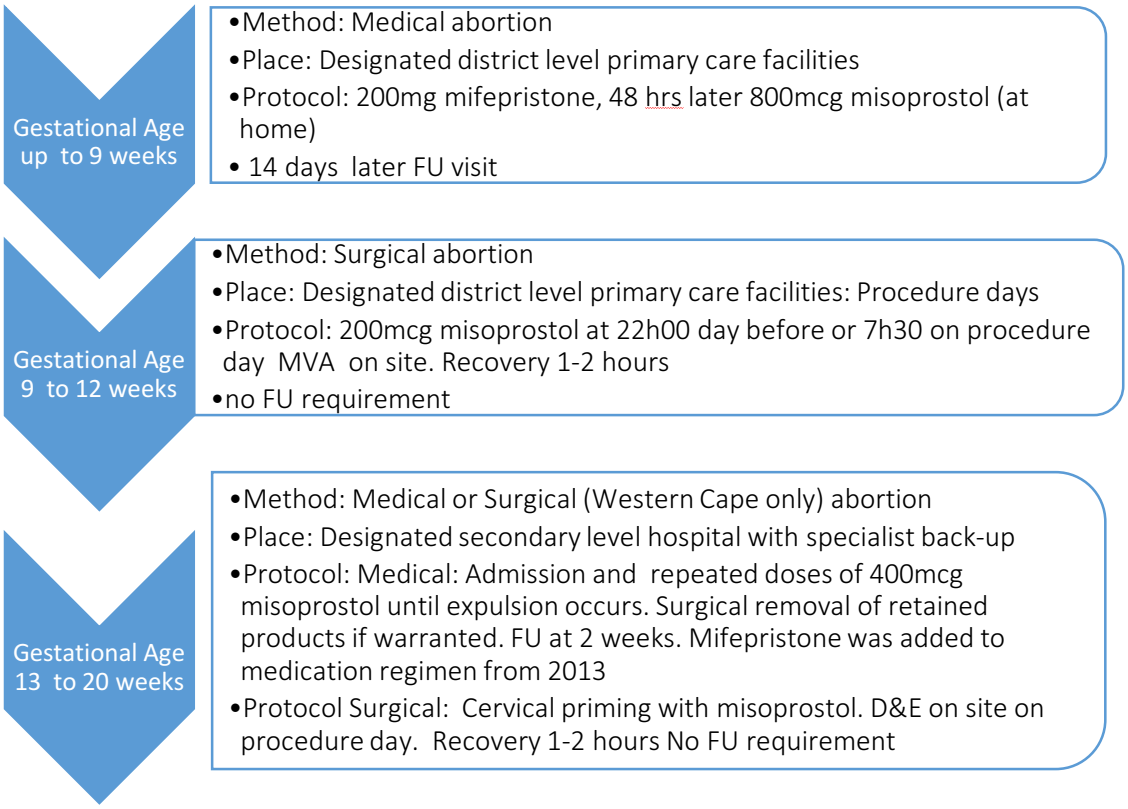
In lower resourced provinces, operational services are often in hospitals rather than in primary care facilities, involving long travel distances for women (24, 27-29). The provision of care out of secondary and tertiary level facilities rather than primary care facilities adds considerably to the cost of rendering the service (28). Health care provider attitudes are reported to be variable; negative, widespread and unregulated refusal to provide care (4, 30, 31), but also positive, supportive attitude among those willing to render abortion care (27, 32). However, there is reluctance to provide services as the GA at presentation increases (33) - a critical issue for service provision in South Africa where a higher percentage of women (>25% in 2014) seek abortion in the second trimester than is generally reported elsewhere (34, 35).

Early on South African policy makers envisioned that introducing medical abortion (MA) with mifepristone into the public sector could address some of the existing barriers to abortion care and help relieve the burden on current services. The South African Termination of Pregnancy (TOP) Implementation Guidelines of 1997 (36) made provision for early MA once it become available, stating "Once medical abortifacients become available in South Africa they should be introduced into the health services to further decentralize services in a safe and effective manner" (36). In 2001 the South African Medicines Control Council (MCC) approved mifepristone for MA up to 56 days GA, which was successfully provided in the private sector (37), but not made available to women attending public health care facilities. Only in March 2010 was a policy decision taken by the Western Cape Department of Health (WCDOH) to introduce MA using mifepristone and misoprostol into the public health sector in the province (38). Since then, with support from various non-governmental organizations (NGOs) assisting with sourcing and supplying mifepristone, as well as with training of providers, the service has expanded to other parts of the country. After some delay, mifepristone was also added to the national Essential Drug List (EDL) for use in second trimester MA in 2012 (39). The mifepristone-misoprostol regimen has since been introduced into the only two public sector hospitals providing second trimester MA services in the Western Cape Province.

Figure 1.1 outlines the protocol for provision of abortion, as formulated in 2010 by the WCDOH (38). Up to 9 weeks GA, the preferred abortion method was MA with mifepristone

which was intended to be accessible at primary care level. The management protocol involved at least two clinic visits at the abortion facility - clinical care in the initial visit included assessment of clinical eligibility, including confirmation of GA with ultrasound, counselling and consent, and administration of mifepristone. A follow-up in-clinic visit at 14 days was for assessment of abortion outcome, entailing a standard pregnancy test, and if indicated (positive test), a clinical examination with ultrasound, if available. A 95% success rate was anticipated (38). Dropping the requirement for a routine follow-up visit only appeared in the WHO guideline in 2012 (40), and thus was never considered in the development of the 2010 WCDOH management protocol.

Figure 1.1 Abortion provision in the public sector WCDOH 2010 guidelines



Development of guidelines for the other provinces in South Africa has been slow, and implementation has lagged further behind this (personal communication, NGO program director, 22 Jan 2016). As official detailed statistics are not available, other sources including reports from sexual and reproductive health (SRH) NGOs, media releases and personal communications with stakeholders working in government and NGOs have been used to

describe the current status of early MA provision. These sources report that first trimester MA services are currently operational in six of the nine provinces, but mostly at centrally located hospitals (personal communication, IPAS national director, KT, 2012, Senior researcher, HERO 24th January 2016 NL, NGO stakeholder, 22 Jan2016, MM). In South Africa, there is no protocol for MA in late first trimester (9-12 weeks). For second trimester MA, at the current time, no facilities in provinces outside of the Western Cape have introduced mifepristone into their services.

1.3 Abortion technologies

Both surgical and medical abortion technologies are safe and effective when performed according to evidence-based accredited guidelines (35, 41, 42). Second trimester abortion carries a higher risk than first trimester procedures, but if managed in safe environments by appropriately skilled practitioners it is still very safe (43) (mortality in the United States (US): 0.6 per 100,000 legal induced abortions) (35). Recommended surgical methods are manual vacuum aspiration (MVA) up to 12 -14 weeks GA and dilatation and evacuation (D&E) for later pregnancies (40). Surgical abortion can be performed by trained nurses for abortion up to 12 weeks GA, and by non-specialist doctors at later GAs (18). MA using the abortifacient RU 486 (known as mifepristone) in combination with a prostaglandin analogue (most commonly, misoprostol) is the most effective medical method and can be provided at primary care level for abortion in the first trimester. As surgical skills are not required, the method has the potential to vastly expand access to abortion services and has particular relevance for low-and middle incomes countries (LMICs) and underserved regions where there is a lack of providers with surgical expertise (44). The regimen is also effective for second trimester medical abortion, which can be largely managed by nurses in facilities where back-up specialist gynecological care is readily available. MA uses simpler technology than surgical methods and involves distinct sub-tasks, making it well-suited to task sharing and self-management (18).

Mifepristone, developed in France in 1988, is regarded as one of the most significant reproductive health technologies to emerge since the oral contraceptive with the potential to transform provision of abortion care (45, 46). The medication is currently provided safely

and effectively to women in more than 61 countries around the world (47). Mifepristone is a synthetic anti-progestin agent that blocks progesterone receptors, preventing the uterus from sustaining embryonic growth, and dilates the cervix. Misoprostol (developed in 1973 for the treatment of gastric ulcer) is a synthetic prostaglandin E1 analogue which causes strong myometrial contractions leading to expulsion of tissue, as well as softening and dilation of the cervix.

1.4 Medical abortion: safety, efficacy, advantages and challenges

The safety and efficacy record of the mifepristone-misoprostol regimen as recently reviewed from large numbers of studies (N >10,000) indicates that the proportion of failed abortions with an ongoing pregnancy is low (0.13-1.1%), and that major complications are rare events (48). Excessive bleeding requiring transfusion is reported at 0.03-0.14%, and infection requiring hospitalization (0.01-0.23%) is associated with using a vaginal route for misoprostol. Ectopic pregnancy is a serious, but rare contraindication (1.3-2% of all pregnancies). However, the prevalence of ectopic pregnancies among women seeking abortion is lower than the overall rate (48).

Legislation adhering to the original labelling protocol for mifepristone of a 600mg dose for use up to 49 days GA has hampered access to MA in many developed countries (48); this was only very recently updated (2016) in the US to 200mg for use up to 70 days GA (49). In contrast to this, in LMICs including South Africa since 2010, government protocols have for some time approved the use of 200mg mifepristone up to 63 days GA, combined with home-use of 800mcg misoprostol for first trimester MA. Misoprostol is cheap, and the use of the lower 200mg mifepristone dose reduces the cost barrier that previously prevented governments' approval in many LMICs for the medication to be made available in the public sector.

Research efforts have explored dosage and the accompanying costs, routes of administration, GA limits and service delivery protocols to establish the most effective safe and acceptable protocols that best suit women's needs, are sparing of health system resources while expanding availability (50). The efficacy of the 200mg mifepristone followed

by a single 800mcg misoprostol dose (4 X 200mcg tablets) regimen decreases as GA advances (42, 51), however using a modified dosage regimen including additional doses of misoprostol for abortion after 9 weeks GA is effective and safe. In these cases, administration of misoprostol should take place in a facility and women should remain there until completion of their abortion (41). Major complications in second trimester MA are uncommon, but include hemorrhage requiring transfusion, uterine rupture, incomplete abortion and infection (43). Thus specialist emergency care should be accessible in facilities providing second trimester abortion services (22, 38, 52). As these events are the same as specialist obstetrician-gynecologists (OBGYNs) manage in emergency obstetric care, second trimester services can be incorporated into hospitals with OBGYN services without the need for major changes (53).

Advantages of MA over surgical methods for first trimester abortion include privacy, control of the process by the woman herself during the home-phase of the abortion, avoidance of surgical instrumentation of the uterus, and the preference for this method by providers (37, 54). While the potential for MA with mifepristone to expand access is widely recognized (55-57), the challenges associated with highly medicalized early service delivery protocols have hampered access and acceptability of the method, and limited its potential to expand access. These challenges included over-cautious limitations on GA eligibility in the first trimester, the requirement for ultrasound (U/S) assessment for GA eligibility and multiple clinic visits to complete the process (58-60). Innovative research has been conducted on service delivery models to simplify regimens, for the most part in the US and Western Europe, and more recently in numbers of LMICs (61-67). These investigators have explored interventions or changes to service provision that eliminate the need for U/S for women seeking abortion, reduce unnecessary clinic visits, and increase women's access and autonomy through self-management of MA tasks.

1.5 Thesis rationale and conceptual framework

In South Africa, studies aimed at informing policy decisions documented a feasible climate for MA introduction and high acceptability of MA among providers and women attending existing public sector surgical abortion facilities. (54, 68, 69). On the strength of local

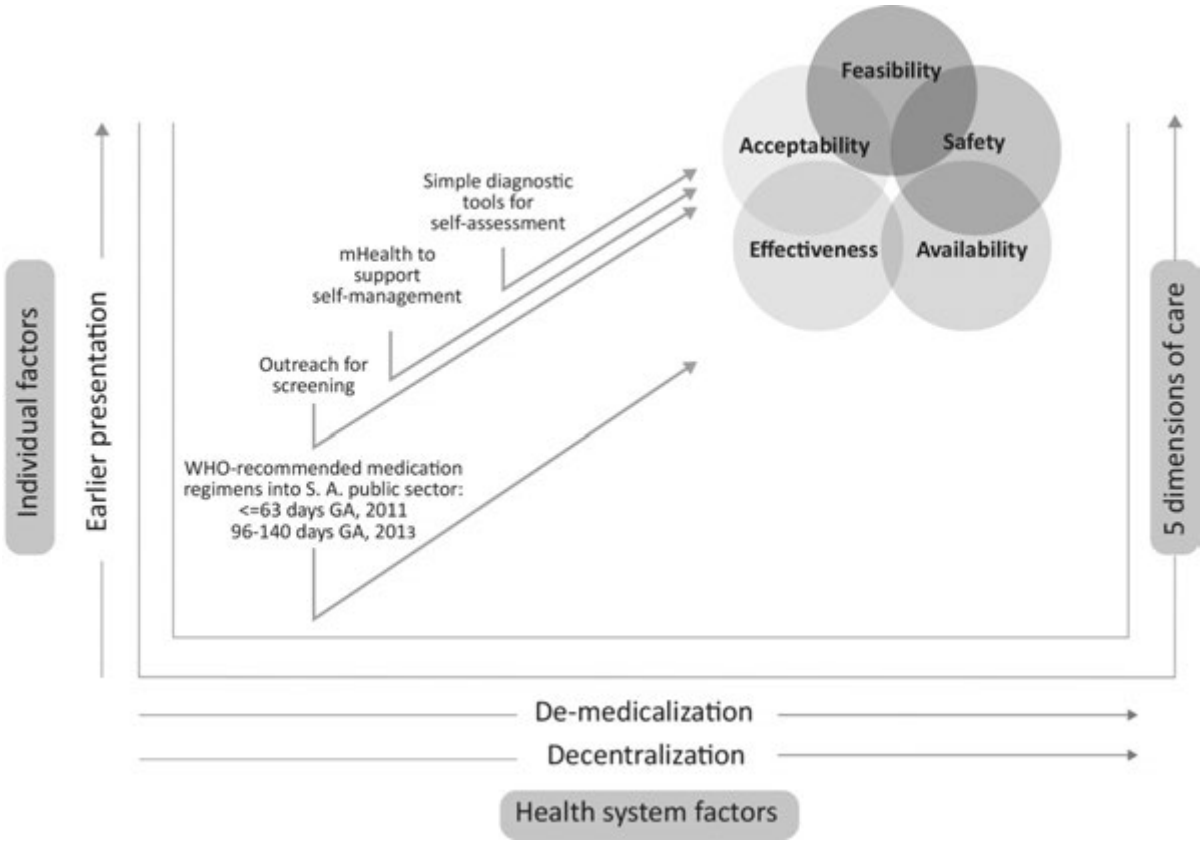
evidence, mifepristone for medical abortion up to 63 day's GA was introduced into limited numbers of primary care public sector facilities in the Western Cape, South Africa in 2011 (38) to be managed and provided by trained nurse-clinicians, and has gradually expanded since then into 6 of the 9 provinces to date (August 2016). In 2012 mifepristone was listed on the EDL for second trimester medical abortion and introduce into the second trimester abortion service in the Western Cape in 2013 and 2014, however no other province offers this service. Research published in 2016 on task sharing eligibility assessment for medical abortion indicated this approach holds promise for the South African context (70, 71). However, evidence across the range of tasks amenable to self-management and informs an overall task sharing strategy to improve access to abortion care is needed. Interventions to support task sharing that are adapted to suit the South African context and evaluated in operational local settings can motivate for future policy decisions and implementation in this regard.

To expand access to MA in South Africa, key research needs are for evidence that can influence program practices, by way of simplifying and strengthening MA provision. In health-care in general the requirement for routine follow-up after clinical procedures is decreasing, and this should extend to abortion care (72). Issues that need to be explored include ways of reaching women with appropriate information and alternatives aimed at simplifying protocols. Additionally, evidence on safety, feasibility and acceptability of task sharing and self-management specific to the country's context is lacking. Finally, evidence on benefits and harms from studies testing interventions to improve service delivery is needed to contribute to the rigor and generalizability of WHO recommendations (18).

The overall conceptual framework for this thesis is illustrated in Figure 1.2, which illustrates factors and strategies that can positively impact on five dimensions of abortion service delivery, namely: feasibility, safety, effectiveness, availability and acceptability. Earlier presentation for abortion care, decentralization of service points and de-medicalization of protocols are individual and health system factors of relevance. The introduction of mifepristone for MA into the public sector facilities was the trigger event for the empirical studies that constitute the thesis. The research in this thesis will evaluate both first and second trimester abortion care subsequent to the introduction of mifepristone, with a

major focus on task sharing opportunities, as well as on outcomes of the new second trimester MA service. The potential for screening by community health workers (CHWs), the value of mobile phone technology as a support mechanism for self-management, and the use of simple symptom questionnaires, checklists and low sensitivity urine pregnancy tests for self-assessment of abortion outcome for first trimester MA will be explored as ways to improve these five dimension of abortion care.

Figure 1.2. Conceptual framework of enabling factors for strengthening health-care



1.6 Thesis aim and key questions

The overall aim of this thesis is to evaluate interventions designed to strengthen and expand safe medical abortion care for adult women attending non-government and public sector health care facilities in South Africa, following the introduction of WHO recommended protocols into the public sector in 2011 and 2013. In this thesis, strategies that involve task sharing and self-management for individual subtasks of MA care are investigated separately;

no evaluation has yet been done where task sharing or self-management of all MA subtasks are combined.

The research aimed to address the following questions, each of which relate to a specific components of MA care.

1. Is it safe and acceptable to replace the ultrasound GA assessment for first trimester medical abortion with last menstrual period dating determined by community health workers?
2. Is an automated timed text message program an effective and acceptable mechanism to provide support to women who are self-managing MA at home?
3. How feasible and accurate is self-assessment of MA completion:
    a. Using a mobile phone questionnaire on symptom history.
    b. Using a low-sensitivity pregnancy test and symptom checklist in combination with text message reminders.
4. What are the improvements in second trimester MA care following the introduction of a mifepristone-misoprostol regimen into the South African public sector service?

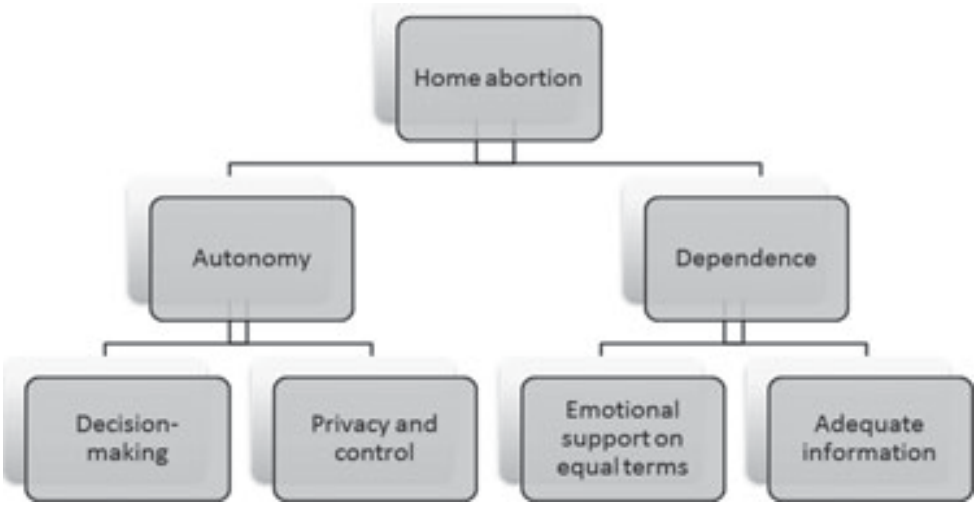
1.7 Theoretical Perspective

Numerous different theoretical perspectives have been used in abortion related research, depending on the purpose of the research in question. Much of the anthropological and social science research has explored the meanings and nature of abortion stigma as well as power dynamics over time and place (73, 74); public health research has tended to focus on determinants of unwanted pregnancies or abortion and biomedical consequences of unsafe abortion and clinical and acceptability outcomes of abortion regimens (21). Examples of research in the South African setting with a specific theoretical perspective include the implementation of the Choice on Termination of Pregnancy Act (CTOPA) from a reproductive rights and human rights perspective (75), and an exploration into provider's perspectives which used the ecological frameworks of Brofenbrenner and McLeroy, Bibeau, Steckler and Glanz, with emphasis on the contested nature of abortion (21).

As nurses mostly provide MA care in health services in South Africa and elsewhere, a theoretical perspective that considers the relationship between self-care and nursing care is helpful. One such theoretical perspective is Orem's Self Care Deficit theory (76), developed by Dorothea Orem (1914-2007), and which has been used to substantiate models of health care including self-management of long-term conditions as well as abortion provision in nurse-driven services (77). The model sees the patient or client as a role player with both agency and responsibility for self-care, with the role of the nurse being to supplement this process where needed, for the most part through counselling and support (77).

The Self Care Deficit theory provides a useful framework for service delivery approaches aimed at shifting the locus of control towards greater client autonomy where possible and away from dependency on health systems. As applied to MA care in a recent study on self-managed abortion in Sweden, components of self-care that constitute an experience of autonomy for women undergoing abortion are balanced against elements of abortion care that entail dependency on providers and which are associated with feelings of vulnerability for women (Figure 1.3) (78). The first autonomous process is the choice of abortion method, an important option, offered in most developed countries. The second autonomous aspect of MA relates to the sense of privacy and control associated with self-administration of misoprostol at home, and the ability to manage the abortion symptoms in the convenience of one's own home.

Figure 1.3 Makenzius' model of home abortion care



(Source: Makenzuis, Scand J Caring Sci; 2013; 27; 569–579)

Dependence (the self-care deficit) is dominant for the components of care where women are reliant on providers: assessment of eligibility, counselling and provision of useful and accurate in-depth information on what to expect when self-managing the abortion process.

The interventions evaluated in the research studies in this thesis aim to increase autonomy and strengthen self-management in abortion care, using a variation of Makenzius' model, appropriate to the South African setting. Differences in South Africa compared to developed country settings are that choice of abortion method is not currently offered - abortion method is determined by health service factors and local protocols as well as overall constraints of resources, particularly of provider availability and time. In addition, in South Africa, control of the process and privacy of the home without provider involvement may not necessarily be desirable to all due to stigma, coercion, family pressure and generally poor living conditions, but could be desirable to most. In busy, overburdened services, as is common in South African public sector facilities, pre-abortion counselling may benefit from further reinforcement, for example using technology (video, internet, text messages) to emphasize and clarify important issues.

1.8 Overview and structure of thesis

Following this introduction, Chapter 2 provides a synthesis and critical review of the published literature on task sharing and self-management of each of the three subtasks for early medical abortion, leading on to an analysis of issues relevant to second trimester medical abortion. Chapters 3 through 7 report the empirical research undertaken in this thesis in the form of five papers, emanating from four research studies conducted during the period 2010 to 2015 (Table 1.1). Each paper addressed a thesis question; questions 3a) and 3b) were addressed in Papers 3 and 4 respectively, question 4 was addressed in Paper 5.

The first study was a sub-study of a multi-country study investigating eligibility assessment for MA by CHWs in South Africa, India and Ethiopia, between 2012 and 2014.The sub-study provided evidence on safety of using last menstrual period (LMP) for GA eligibility for MA from the South African context and identified selected women in whom LMP can be used safely to confirm GA eligibility for self-managed MA. In-depth interviews furnished provider's and community health worker's perspectives on task sharing GA determination. The second study measured the effectiveness and acceptability of an automated text message program to support women while self-managing their abortion. Study 2 also evaluated the feasibility and accuracy of self-assessment of medical abortion outcome using mobile phones to do an automated questionnaire, which is reported in Paper 3. Study 3 evaluated a new low sensitivity urine pregnancy test for ease of interpretation in the South African context. Usability was compared for different counselling modes. Study 4 documented changes in service delivery following the introduction of mifepristone into medical abortion services in the public sector in South Africa. The five papers have been prepared as separate chapters in this thesis, either in the form of manuscripts submitted for publication or as published papers during the period of the PhD.

Table 1.1 Summary of studies and methodologies

Research study	Chapter (Paper #)	Publication	Component of care	Methodology
1	3 (1)	**Accuracy of gestational age estimation from last menstrual period among women seeking abortion in South Africa, with a view to task sharing**	GA estimation for self-managed MA	Mixed methods, Analysis of safe cut-offs for using LMP-based GA and in-depth interviews
2	4 (2)	**Mobile phone messages to provide support to women during the home phase of medical abortion in South Africa: a randomized controlled trial**	Self-administration of misoprostol and self-management of the abortion symptoms	RCT comparing standard self-managed care to supported self-managed care
2	5 (3)	**Assessment of completion of early medical abortion using a text questionnaire on mobile phones compared to a self-administered paper questionnaire among women attending four clinics, Cape Town, South Africa**	Self-assessment of MA outcome	Feasibility study including analysis of accuracy of self-assessment of MA outcome
3	6 (4)	**Self-assessment of medical abortion outcome in South Africa: A non-inferiority, randomized controlled trial**	Self-assessment of MA outcome	RCT comparing 2 modes of service delivery for self-assessment of MA outcome
4	7 (5)	**Clinical outcomes and women's experiences before and after the introduction of mifepristone into second-trimester medical abortion services in South Africa**	Second trimester MA	Repeated cross-sectional survey of clinical outcomes and acceptability

The final chapter, Chapter 8, draws the separate studies together, and discusses the findings for the research as an integrated whole. The limitations of the work are addressed and a number of key issues are discussed with relation to the thesis conceptual framework (Fig 1.2). Recommendations for future research are made, and conclusions are presented based on the research findings overall.

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Chapter 2 Literature Review

2.1 Introduction

This literature review aims to describe and appraise the published literature on ways of strengthening the provision of medical abortion (MA). The objective is to identify evidence that can inform interventions and strategies for strengthening MA in the South African public sector setting and other similar contexts.

The WHO framework for task sharing and self-management in MA care is introduced, followed by an overview of studies on the feasibility, acceptability and effectiveness of using mobile phone technology to strengthen health-care delivery in developing country settings, with specific reference to reproductive health-care. Thereafter the chapter is organized into sections that address the three key activities for task sharing and self-management in early MA care, and a fourth section that reviews second trimester MA care using the combined mifepristone-misoprostol regimen. The respective topics for these four sections are as follows:

1. Estimation of gestational age without ultrasound among women seeking abortion
2. Self-administration of misoprostol and self-management of MA
3. Assessment of early MA completion
4. Second trimester MA care with mifepristone and misoprostol

Within each section the published literature is reviewed according to themes. A chronological approach is used where appropriate to understand developments that have taken place in the field.

The literature pertaining to topics 1) and 2) above, is reviewed to gain an overall understanding of the safety, feasibility and acceptability of task sharing these activities from other settings and to identify novel approaches not previously investigated. For topic 3), the literature is reviewed in greater detail than that for the other topics, as this motivates for the two MA self-assessments evaluated in this thesis, which constitute a major part of the research reported here. The final section of the chapter addresses topic 4), and documents the accumulated evidence, mostly from developed country settings, for improving efficacy,

acceptability, quality of care and convenience in second trimester MA care with mifepristone and misoprostol. This section concludes with some evidence from LMIC settings including options for task sharing and self-management.

For all sections of this review, the published literature was searched using Google, PubMed, Google Scholar, EBSCOhost, Medline and POPline. Searches were updated in August 2016 to include the most recent literature. Systematic reviews, randomized control trials, cohort, case-control and cross-sectional studies were included as well as reports from grey literature. The searches were limited to English articles. Reference lists of key articles were checked to identify relevant studies not included in the online searches. Specific terms were used alone and in combination for the different sections, and are listed in the respective introductions in this review. More detail is provided for the search relating to topic 3) as this section aimed to identify all published evidence on simplifying and task sharing assessment of medical abortion outcome. A meta-analysis of these published studies was not attempted due to the varying study designs and outcomes.

2.2 Task sharing and self-management in medical abortion

For MA to realize its full potential in expanding access to safe abortion, service delivery models need to be simple and convenient. Limited acceptance of MA by both women and providers has in part been due to the highly medicalized early service delivery models, which involved multiple clinic visits at an abortion facility (1, 2). A four-visit protocol was subsequently shortened to three, and then to two visits in most countries, including South Africa (3-6).

Compared to surgical methods, MA using mifepristone in combination with misoprostol simplifies the requirements in terms of place, equipment and skills of the HCW providing the abortion (7). In first trimester abortion care, provider care for the two-visit protocol involves establishing eligibility, counselling on women's options and if she consents, on the timing and administration of the drugs. At follow-up the provider establishes the abortion outcome, and is responsible for correct management of ongoing pregnancy or incomplete procedures, and efficient referral for major complications such as heavy blood loss requiring transfusion. Back-up MVA is required for only a small percentage of women with ongoing

pregnancies or if additional doses of misoprostol are unsuccessful for incomplete procedures. In some cases, MVA is offered for retained products or requested by women for persistent bleeding. Thus MA in the first trimester is well-suited to lower levels of the health-care system and to self-management by women where there is an established referral system and a small or centralized pool of providers with surgical expertise to manage rare ongoing pregnancies (8).

The WHO has provided a framework identifying component activities or subtasks of abortion care that may be shared with CHWs or self-managed by women (7). These subtasks for early MA provision include eligibility assessment; administration of medication according to instruction (for the combined mifepristone and misoprostol regimen or misoprostol alone if mifepristone is not available); and 3) assessment of completeness of the abortion.

Figure 2.1 Women's role in managing the process of medical abortion

Woman's role	Recommendation	Justification
Managing the entire process of medical abortion up to 84 days	No recommendation for the overall package; recommendations made for subtasks as below.	Individual components of the self-management of medical abortion have been tested; however, there is as yet insufficient evidence on using all three components together.
Self-assessing eligibility for medical abortion	Recommended within the context of rigorous research 	Women may be more conservative in assessing eligibility using simple checklists (low certainty). However, the approach is promising and further work is needed on developing appropriate assessment tools.
Managing the mifepristone and misoprostol medication without direct supervision of a health-care provider	Recommended in specific circumstances  We recommend this option in circumstances where women have a source of accurate information and access to a health-care provider should they need or want it at any stage of the process.	There is evidence that the option is safe and effective (low-certainty evidence from numerous studies, but using non-randomized designs given the strong preferences of women for one or the other option). More women report the method to be satisfactory when it is self-managed (low certainty). Women find the option acceptable and feasible (high confidence) and providers also find the option feasible (high confidence).
Self-assessing completeness of the abortion process using pregnancy tests and checklists	Recommended in specific circumstances  We recommend this option in circumstances where both mifepristone and misoprostol are being used and where women have a source of accurate information and access to a health-care provider should they need or want it at any stage of the process.	There is evidence that the option is safe and effective including in low-literacy, low-resource settings (moderate to high certainty).

Source: Health worker roles in providing safe abortion care and post-abortion contraception (7: p41)

The recommendations for task sharing with CHWs is for abortions performed up to 10 weeks GA and for self-management of abortions, up to 9 weeks GA. Generally, the WHO concludes that the benefits outweigh harms if these activities are task shared, but cautions that further rigorous and context- specific research is needed for each subtask. Specific research needs include context-specific evidence on feasibility, safety, effectiveness and acceptability of task sharing and self-management, as well as refinement of tools, methods and protocols to be used by CHWs or by women (7). In addition, studies are needed that identify effective strategies to strengthen implementation of task sharing in national and provincial programs (7).

The opportunities for task sharing MA after 10 weeks GA are limited due to the increased risk of complications associated with abortion as pregnancy progresses (9). For MA in the late first trimester (11 – 12 weeks GA) and in the second trimester, task sharing with CHWs or self-management has not been recommended by the WHO. Protocols and guidelines generally hold that monitoring and care from the time of misoprostol to abortion completion should be in-facility but can be provided by nurses rather than physicians. There should however be surgical backup and infrastructure for managing any complications that might occur (7, 10, 11). The WHO task-shifting recommendations are silent on off-site self-administration of mifepristone prior to admission for MA after 10 weeks GA, however this has been identified elsewhere as a beneficial service delivery option(12). The WHO recognizes the need for further research into safety, efficacy and feasibility of nurses providing care for abortion after the first trimester (7).

Self-management of specific components of MA care can empower women, giving them increased autonomy and a sense of control over their abortion procedure (12-14). However self-management of MA should be optional, and access to care when needed should not be compromised where programs incorporate self-management options (7). Novel approaches that can support women's self-management or CHW activities in abortion care include the use of digital technologies such mobile phones, as discussed below,

2.3 mHealth in health-care and abortion care

Offering support via mobile phones (mHealth) has shown promise as a means of strengthening health care delivery in many different fields, and has relevance for MA provision. The fundamental benefit of mHealth is that the access to information on healthcare is shifted from a centralized location to where the person needing this care is located, as long as connectivity is adequate. While mHealth is a relatively new approach to strengthening health-care, research has demonstrated its potential to strengthen health systems through improving access to health information and care, in some cases for diagnostics, and for treating and tracking health conditions (15). The published literature has shown that mHealth can effectively support behavior change, disease management and self-management, although the added value for ultimately improving health outcomes is limited (16-20).

The majority of mHealth interventions using text messaging via short message service (SMS) on mobile cellular phones have been conducted in developing countries, in Africa and Asia (19). In Africa, most projects were in South Africa and Kenya, followed by Tanzania and Uganda - countries where infrastructure is relatively strong and handset ownership is high (19). In South Africa, for example, mobile cellular subscription penetration has steadily increased and is currently very broad based – reported to be more than 100%. This figure counts both multiple and individual subscriptions, thus it overestimates the number of individual subscribers (21).

Commonly targeted reproductive health-care issues using SMS support programs in developing countries include HIV/AIDS, SRH and MNCH (18, 22-24). The majority of projects indicate some success for improved compliance with health-care regimens and self-management of long term conditions (20, 25) and generally the programs are very acceptable to participants (19), although significant improvements in health outcomes are harder to demonstrate (20). There was no published research on the use of SMS to support self-management of abortion care at the time that the intervention in Study 2 (this thesis) was designed (December, 2010). A publication emanating from research project 2, but not included in the thesis, reported strongly positive responses from women who had received

SMS support (26). Other mHealth initiatives have demonstrated feasibility, acceptability and effectiveness in strengthening aspects of abortion care, and are reviewed in more detail in the relevant sections of this chapter (27-34), (Gerdts, C et al. Manuscript in preparation, 20/08/2106). Overall, there appears to be scope for mHealth to support MA, and with South Africa's technology infrastructure and handset ownership, it is a setting that is well-matched regarding feasibility for this type of intervention.

The remainder of this chapter reviews the published literature related to strengthening task sharing for each subtask in early MA, as identified in the WHO framework (Fig. 2.1). As each subtask involves different activities, each with a distinct body of published research, separate literature searches and reviews were performed for each subtask individually. Similarly, the findings from the published literature on strengthening second trimester MA provision are reviewed in a separate section in this chapter.

2.4 Task sharing and self-managing gestational age estimation in abortion care

2.4.1 Search Terms

Literature search terms used alone and in combination for this section included "gestational age", "last menstrual period", "medical abortion", "abortion", "accuracy", "eligibility", "estimation", "eligibility", "bimanual palpation" and "ultrasound".

2.4.2 Introduction

The requirement for an ultrasound (U/S) examination to determine gestational age with accuracy is based on the need to provide a safe abortion. Gestational age (GA) is a major determinant of whether or not a woman seeking an abortion can have one (legal GA limits), where she should have one (primary care or hospital), what method might be offered to her (medical or surgical), how effective the procedure is expected to be and what symptoms she can expect (bleeding and expelled products). Where abortion care is largely self-managed, correct estimation of GA assumes greater importance in ensuring a safe and successful procedure. Nonetheless, the requirement for an U/S examination for first trimester MA

hinders access to the service and limits availability to settings that have both the equipment and health-care professionals (HCPs) with the requisite expertise to use it (35).

The published literature on GA estimation without U/S among women seeking abortion is from diverse settings, and differences in methods used for GA determination, different inclusion and exclusion GA criteria, and changes in gestational age limits for MA eligibility limit the scope for comparison. Nonetheless, some large studies and two recently published reviews have concluded that U/S is unnecessary in most cases for determining eligibility and providing a safe medical abortion in the first trimester (36-38), but have generally concur that further context-specific research is needed (7).

2.4.3 Methods used for gestational age determination

The different methods of GA determination include those based on women's self-reported unprotected intercourse or the first day of her last menstrual period (LMP) or clinical methods requiring HCP expertise (39-41). Self-reported methods involve two steps; recall of the event and calculation of the number of days to the current date. LMP dates are more accurate than women's estimates of pregnancy duration or date of unprotected intercourse (41, 42). Calendars, pregnancy wheels or calculators used by trained personnel are helpful in calculating the number of days from the LMP date (41), however electronic calculators are more accurate for working out GA from LMP than paper based pregnancy wheels, which are prone to small, but regular manufacturer and user error (43, 44).

Clinical methods include bi-manual palpation or ultrasound, performed by trained HCPs. Accurate measurement with U/S is considered the "gold standard" for GA dating, although in advanced pregnancies, the accuracy of all clinical methods decreases due to normal biological variation in size of the fetus (36, 45). Very early pregnancies (< 6 weeks GA) are also more difficult to date accurately using clinical methods (40). Reasonable agreement with few extreme differences has been documented for GA from bi-manual palpation compared to GA by U/S. (41, 46). Experience with bimanual examination generally improves accuracy (47, 48), although HCPs providing MVA who are most familiar with assessing whether pregnancies are more or less than 12 weeks, may need further training for earlier GA estimation (41). Indeed, some studies have demonstrated that LMP-based GA in early

pregnancy (GA <12 weeks) can be more accurate than provider bi-manual examination (39, 41).

2.4.4 Variation in gestational age in study populations

Some of the discrepancies in accuracy of GA estimation from LMP across studies can be ascribed to the use of different GA limits for inclusion into the study population. As can be expected, recall of LMP is more accurate among women in early rather than later pregnancy, and studies that only include women seeking abortion with a GA within 63 days usually demonstrate very accurate recall of LMP (42, 49). Among women seeking abortion in the late second trimester, GA has been substantially underestimated (50). This has significance for the South African context where more than 25% of abortions performed are in the second trimester (51). In addition, providers also need to be mindful that women seeking abortion tend to underestimate their GA compared to women of similar GA wanting to take the pregnancy to term (52).

2.4.5 Changes in gestational age eligibility limits for medical abortion

The GA limit for self-managed first trimester medical abortion has been extended from 49 days when MA was first introduced to 70 days in some countries (53). The proportion of women likely to be incorrectly assessed as eligible using LMP dating, but over the GA limit according to U/S dating –defined as the "caution zone" (42) - depends not only on their accuracy of LMP recall, but also on what GA is used for the eligibility cut-off (49, 56, 63 or 70 days) (36, 38, 41, 42, 54, 55). In the earlier South African study comparing LMP- to U/S-based GA with using a cut-off of 56 days GA, 31.6% of women seeking abortion underestimated their GA by more than two weeks and 12% were in the caution zone (41). In contrast, a large US study of abortion seekers (n=4257) found that only 1.6% were in at the caution zone (at 63 days) (38). Of note in the US study is the very low percentage of women with later gestations (38) compared to the South African study (41).

Extending the GA eligibility cut-off to 70 days increases the proportion of women eligible for early MA. The recent approval (March 2016) of mifepristone for early MA up to 70 days GA by the US FDA bodes well for a similar extension in other settings including South Africa (53). In terms of efficacy, MA with mifepristone and misoprostol decreases after 49 days GA, but is effective up to 70 days GA (56) with a slightly lower success rate at 9 and 10 weeks

compared to earlier gestational ages (57-59). Recent trials conducted in various settings worldwide reported success rates (complete abortion with no need for additional surgical intervention) between 92% and 93% for women in their 10th week of gestation, and slightly higher for those using a higher dose of misoprostol (56, 60). There was significantly more bleeding and more MVAs performed for bleeding among those with GA=10 weeks compared to GA=9 weeks, however these differences were very small (60). The main implications of the studies were that safety and efficacy was not significantly compromised by extending MA up to 10 weeks GA. Importantly, this can be offered to women without the need to alter existing services, but can be safely self-managed at home (56, 60). Assuming that the 70-day limit may be approved for South Africa in the future, the analysis of LMP-based GA for this thesis (Study 1, Chapter 3) will use both a 63-day as well as 70-day cut-off for GA eligibility for first trimester MA.

2.4.6 Recent South African studies

The 2010 Western Cape DOH MA protocol required an U/S examination to be performed to establish gestational age if medical abortion is to be provided (6). Two recent published studies that include South African women seeking abortion have evaluated accuracy of GA from LMP (34, 35). In the first study (the parent study to Study 1, this thesis), CHWs estimated women's GA using LMP and a pregnancy wheel. These results were compared to GA from provider bi-manual examinations (35). The other study used custom-built website for women to self-determine their GA from their LMP date (34). These studies showed varying results (8% and 4%, respectively) for proportion in the caution zone (cut-off: 63 days). However, both had limitations; firstly, variable accuracy with the bimanual method was found (35), and the second study used a small sample and some women had an U/S examination prior to enrollment (34). The findings from these studies, combined with the recent reviews (36, 37) and the WHO task-shifting guidelines (7) indicate the need for further evidence to identify criteria for the safe use of GA estimation from LMP in the South African context, and to inform guidance on the safety of task shifting and self-assessing GA eligibility for early MA.

Implications for moderate underestimation of GA using LMP are that a procedure may be drawn out, involve more side effects, but is unlikely to be unsafe among most women. In

contrast, overestimation may result in denial of care, or unnecessary referral to HCPs with requisite clinical skills (46). Studies have recommended GA from LMP can be used to determine eligibility for safe self-managed MA for selected cases. A two week error margin for estimated GA from LMP and establishing factors associated with accurate recall of LMP are reported as promising ways to maximize benefits and reduce harms (36, 37).

2.5 Self-administration of misoprostol and self-management of medical abortion

2.5.1 Search Terms

Literature search terms used alone and in combination for this section included "acceptability", "anxiety", "emotional distress", "depression", "abortion", "medical abortion" "psychometric instruments", "eligibility", "misoprostol" and "home-use".

2.5.2 Acceptability and preferences

The literature from diverse settings on the acceptability of self-administration of misoprostol and self-management of MA at home, in both quantitative and qualitative studies, has generally indicated high levels of acceptability (61-63). However, when MA was first made available, women's preference for home or clinic administration of misoprostol varied between settings. Earlier studies in the UK and China reported women's preference for clinic rather than home-use of misoprostol (62), but other and more recent studies from settings where a choice was offered, including the USA, Sweden, Vietnam, and India reported a preference for and a high level of satisfaction with home-use of misoprostol (4, 49, 64-66).

Providers from many different contexts have generally been in support of home-use of misoprostol, despite some concerns around medication compliance and possible delayed identification of problems (63). Familiarity of providers with the safety of home-use by women has increased acceptability (63). In South Africa, an early feasibility study reported support for home-use of misoprostol from both policymakers and providers (67). The majority of women seeking abortion were interested in trying MA with home-use of misoprostol (82%), despite a minority being eligible in terms of their GA (67). A subsequent operations study showed that the majority of women choosing MA over MVA opted to use misoprostol at home (68).

Logistical issues commonly reported by women who favor home-use of misoprostol included resource saving, pressure of family and work commitments, and having control of scheduling (69). In addition, issues of choice, control and ownership of the process have also been described (70). Control of privacy and involvement of partners or others in a supportive role at home is seen as a major factor in women's preference for and their acceptability of home abortion. Autonomy and choice on this matter is considered to be important (14, 55, 71). While there is clear evidence of the many positive aspects of home-use of misoprostol and self-management of MA, studies have also indicated that women have concerns around management and safety of the procedure and experience anxiety during the process (72, 73).

2.5.3 Emotions experienced while self-managing medical abortion at home

Research into adverse emotional states associated with abortion has consistently and rigorously demonstrated that emotional distress is largely related to the unwanted pregnancy, to anxiety experienced while seeking the abortion, to predisposing emotional traits, and that pre-abortion anxiety is largely alleviated following a successful abortion procedure (74-77).

Distinct from the above issues, are women's emotional experiences while self-managing MA at home. Research has shown that women undergoing successful MA are generally very satisfied with their abortion, however they do have concerns around management and safety of the procedure (72, 73). Thus, counselling and education assume greater importance with home-based misoprostol as the woman plays a more active role in the process (63, 78). Beyond the physical experience of the MA process, acceptability and satisfaction also depend on emotional and other forms of support during procedure, as well as pre-procedure counselling on what to expect (61, 63, 79). Hence, amendable factors determining acceptability of self-management of MA for women involve forms of psychosocial support and adequate preparation (80).

2.5.4 Support for self-management using mHealth

The development of an SMS intervention to provide support to South African women self-managing their abortion in early 2011 (Study 2, this thesis) was informed by the published

literature available at the time and by the findings from an on-site needs and context assessment (26). Results published outside of this thesis documented women's subjective experiences and reactions to the messages. For example, women said the SMSs addressed their concerns with respect to the MA process, provided them with some support and comfort, and allayed anxiety for partners fulfilling a supportive role. Few women had negative responses, stating the messages reminded them of a negative experience (26).

Other research on strengthening abortion care confirmed women's preference for and the utility of using text messages in place of a telephone call or clinic visit with a provider. (31) (Gerdts, C. et al. Manuscript in preparation, 20/08/2016). However, the primary purpose of the messages in both these studies was to confirm a successful, safe procedure rather than to provide support for the procedure.

2.6 Self-assessment of early medical abortion outcome

2.6.1 Introduction

The need for a safe and effective self-assessment of MA outcome has generated a large body of research, focused on alternatives to the in-clinic follow-up visit with U/S. Studies 2 and 3 (this thesis) drew extensively from this literature to design a suitable self-assessment package for use in the South African context. A synthesis of the published research is presented in Table 2.1. An accompanying chronological outline is presented of the studies which, prior to 2011, informed the development of the self-assessments for Study 2 (Chapter 5) and subsequently informed Study 3 (Chapter 6) which commenced in 2014.

2.6.2 Search strategy

The PubMed database was searched using the following search terms; ((medical AND abortion) OR (pregnancy AND termination) OR (menstrual AND regulation)) AND ("1950/01/01"[PDat] : "2016/12/31"[PDat]))) OR ((abortifacient OR RU486 OR "RU 486" OR Cytotec OR Misoprostol OR Mifepristone) AND ("1950/01/01"[PDat] : "2016/12/31"[PDat]))) AND ("1950/01/01"[PDat] : "2016/12/31"[PDat]))) AND (((((outcome OR success OR follow-up) AND ("1950/01/01"[PDat] : "2016/12/31"[PDat]))) AND ((assess* OR self-assess* OR self-manage* OR ((out) AND (of) AND (clinic))) AND ("1950/01/01"[PDat] : "2016/12/31"[PDat]))) AND ("1950/01/01"[PDat] : "2016/12/31"[PDat])) Filters: Publication date from 1950/01/01 to 2016/12/31. Updated searches include

results as at 15 August 2016. No language restriction was used, and publication dates were limited to post-1950 as an arbitrary starting date soon after the UN human rights declaration of 1948. The original search results identified 1676 articles. Summaries that were in English were reviewed for relevance and 24 studies were identified as pertinent to this review. Two additional study were added between May and August, 2016. Studies included are shown in Table 2.1 which summarizes the study context, follow-up assessment modality, results of assessment method, conclusions and limitations of the 26 included works.

2.6.3 Developments in self-assessment for medical abortion

While there are some earlier studies motivating for evidence (39, 49) on alternatives to then current protocols for assessment of MA outcome, the numbers of studies evaluating interventions increase substantially after 2000. Relevant studies published after 2000 and prior to Study 2 of this thesis took place in the US with one exception, which reports from various countries, usually restricted settings, but which are unnamed (27). Early efforts aimed to dispense with the U/S requirement for determining MA outcome while maintaining an in-clinic assessment based on either provider's or provider's together with women's evaluation (81, 82). The primary outcome used in these studies was complete abortion and both studies were inadequately powered to detect ongoing pregnancies (a limitation that pertains to most studies, to date). The reported sensitivity was high and specificity low for pregnancy expulsion, however the clinically relevant outcome of incomplete MA or ongoing pregnancy was not evaluated (Table 2.1). Clinician's assessment was not standardized which limited generalizability and repeatability of results. Self-assessment using a suitable urine pregnancy test (UPT) was proposed (83), however early versions of low sensitivity urine pregnancy tests (LSUPTs) were inaccurate, and standard high sensitivity urine pregnancy tests (HSUPTs) used within 1-2 weeks of first medication were known to have a high false positive rate (84, 85).

Research into follow-up alternatives that would strengthen medical abortion provision initially continued to focus on provider-assisted modalities (86). Differences compared to earlier approaches included exploring whether clinical history to establish ongoing pregnancy or abortion complications could be conducted by phone, rather than involving an in-person clinic visit (87).

Table 2.1 Studies on alternatives for assessment of MA outcome

Article	Setting	N enrolled, LTF	Assessment performed by	Assessment method	Study design GA limit	Result of primary outcome	Conclusions	Limitation
Pymar et al. 2001 (81)	1 center US	N=40, LTF =0%	Women + In-clinic provider:	Clinical history at 14d for passing of gestational sac vs U/S	Prospective study. GA: ≤49 days	Clinical history: 95% sensitivity, 67% specificity for expulsion of gestational sac	Clinical history taking by HCP is mostly accurate to determine MA outcome	Validity tested for expulsion -not most important O/C. Convenience sampling. Small sample
Rossi et al. 2004 (82)	Multi-center US	N=1080, LTF~14%	Women + in-clinic provider	Clinical history at 7-12d for passing of sac vs. U/S	Sub study of RCT. GA: ≤63 days	Clinical history: 97% sensitivity, 31% specificity PPV =99% for expulsion of pregnancy.	No physical exam or U/S needed to establish MA outcome	Validity tested for expulsion -not most important O/C. History taking not standardized so not generalizable or repeatable.
Grossman et al. 2004 (83)	N/A	69 studies included	Various alternatives to in-clinic provider care	Remote FU suggested : Telephone / Instruction sheet or home UPT	Commentary and review	Identified potential for telephone call/Instruction sheet/home UPT except for at-risk cases such as uterine anomalies	In-clinic FU probably only needed for at-risk cases	N/A
Godfrey et al. 2007 (85)	Multi-center US	N=2160, LTF 23% and 43%	Self-assessment vs. in-clinic provider care	LSUPT 2000mIU/ml and HSUT 25mIU/ml vs. U/S at 7d and 14d	RCT. Percentage false neg. and false pos. vs. U/S GA: ≤63 days	LS tests: 0.2% false neg. 60.8% false pos.at 14d. HS tests: 0.3% false neg.; 65.8% false pos. at 14d.	These LSUPT and HSUPTs are not useful due to high false positive rate	Early version of tests Testing done at 7d and then 14d when there was high LTF
Gomperts et al. 2008 (27)	Multi-country	2 cohorts: N=484 LTF~ 45% N=174 LTF=22%	Provider-assisted; out of clinic	Standard online symptom checklist, email and phone consultation with provider where needed.	Prospective follow-up of 2 cohorts GA: ≤63 days	Cohort1: Outcome of MA: 1.6 % ongoing pregnancies, 14% MVA for bleeding/incomplete Cohort 2: Outcome of MA: 0% ongoing pregnancies, 7% MVA for bleeding/incomplete	Despite high LTF, proportion of ongoing pregnancies and cases having MVA for bleeding consistent with other reports for MA	High LTF, which could bias results. Complications could be missed

Clark et al. 2010 (86)	Multi-center US	N=4091, LTF~25%	Self-assessment + in-clinic provider:	LSUPT at 7-14d and symptom checklist and provider PE vs U/S	Best fit algorithm based on adding questions, LUSPT and provider PE GA: ≤63 days	LSUPT: 80% sensitivity. Full algorithm best for detecting ongoing pregnancy or need for additional care. Tradeoff between sensitivity and specificity for algorithms	Self-assessment + in-clinic provider PE as good as U/S	LTF ~20%, Retrospective comparison of U/S and algorithms
Perreira et al. 2010 (87)	1 center US	N=139, LTF: 0%	Provider-assisted; out of clinic	Standardized questions in telephone call with provider at 7d, HSUPT at 30d	Prospective, feasibility study GA: ≤63 days	95% sensitivity, 50% specificity for expulsion of pregnancy. Outcome of MA: 3% ongoing pregnancies	Telephone call to provider followed by HSUPT at 30d feasible alternative to U/S or serum hCG	30 days is too long for MA confirmation, as ongoing pregnancies can advance beyond 12 weeks. Not generalizable outside of US
Grossman et al. 2011 (88)	US and Europe	8 studies included	Self-assessment and provider assisted, out of clinic	Serum hCG, symptom checklist +LSUPTS, telephone consultations as alternatives to U/S	Systematic Review of published literature.	Calculation from studies included: sensitivity, specificity, PPV, NPV to detect ongoing pregnancy or retained gestational sac	Accuracy and feasibility of home-based UPTS especially shows promise - and needs to be further researched	Small number of studies included. Included studies not powered to detect primary outcome. All from developed countries, US and Europe
Jackson et al. 2012 (89)	Unclear if 1 center US	N=106, 1 to 1 ratio	Provider assisted self-assessment; in-clinic	Standardized symptom checklist at 7-14d vs. U/S	Case Control. Cases had MVA for retained pregnancy or gestational sac. Controls had complete MA confirmed by U/S. GA: ≤63 days	67.9% sensitivity, 79.3% specificity for on-going pregnancy or retained gestational sac.	Symptoms alone not sufficiently accurate for assessment of failed MA	Retrospective study. Potential stated for selections bias. Ratio of cases to controls not in proportion to outcome of interest
Blum et al. 2012 (90)	Multi-center US	N=490, LTF~14%	Self-Assessment out of clinic vs. in-clinic provider assessment	SQUPT at 7d dBest® (AmeriTek Inc., Everett, WA, USA) and symptom checklist vs. any of: physical exam, serum hCG, U/S	Prospective cohort and user comprehension survey. GA: ≤63 days	SQUPT: 100% sensitivity, 97% specificity for on-going pregnancy. 91% easy to use	SQUPT valid option to replace in-clinic FU. Programmatic application need further research	Participants misunderstood question on whether or not clinic follow-up was necessary
Cameron et al. 2012 (91)	1 center Scotland	N=476, LTF ~13%	Provider assisted self-assessment; out of clinic	LSUPT (Babycheck Duo, 1000mIU/ml threshold) with	Service delivery evaluation,	LSUPT +Telephone call: 75% sensitivity, 88% specificity for ongoing	LSUPT+ telephone call at 2 weeks effective	Small possibility of missing ongoing

				pictorial instructions +CL at 14d + standardized questions by telephone call with provider at 14d	acceptability survey; GA: ≤63 days (3 had GA >63 days)	pregnancy. Acceptability survey showed all preferred this modality for FU.	and preferred by many women	pregnancies in LTF group.
Park et al. 2013 (92)	Multi-center Vietnam	N=258, LTF~23%	Women + In-clinic provider clinical history telephone consultation at 14-20d	Telephone consultation +UPT (type not stated) at 14-20d	Service evaluation. MA outcomes reported	65% returned for in-clinic assessment. 0.5% ongoing pregnancies, 8.7% incomplete MA with retained products	Follow-up should be strengthened. Helplines useful where MA possibly unsuccessful esp. following unsafe abortion	MA outcome not validated against in-clinic provider assessment. Limited to private providers
Lynd et al. 2013 (93)	1 center Vietnam	N=297, LTF~1.5%	Self-assessment vs. in-clinic provider	SQUPT and symptom checklist vs. physical examination and U/S at 14d	Prospective cohort and user comprehension survey.	SQUPT+CL: 100% sensitivity, 90% specificity for on-going pregnancy. 87% easy to use. 42% with decreased hCG were unsure whether needed to return to clinic	SQUPT feasible, highly sensitive and specific. Clear provider instructions important	One hospital only, most had completed secondary education
Bracken et al. 2014 (31)	Multi-center UK	N=978, LTF~28%	Self-assessment out of clinic vs. in-clinic provider	LSUPT (NADEL, 2000mIU/ml threshold) with 4 standardized questions by SMS or telephone call by non-clinician at 14d vs. physical examination + U/S	RCT: remote vs in clinic provider Effectiveness, and feasibility to improve FU. GA: ≤63 days	LSUPT+CL: 100% sensitivity, 85% specificity for on-going pregnancy. LSUPT100% sensitivity, 94% specificity. FU rates no different between groups. Remote FU preferred	LSUPT suitable alternative to In-clinic FU. CL triggers unnecessary in-clinic FU	Underpowered to detect ongoing pregnancy. Not generalizable as clinic SOC may be different to other settings.
Michie at al. 2014 (94)	1 center Scotland	N=943 (933) , LTF~30%	Provider-assisted self-assessment; out of clinic	LSUPT (Babycheck Duo, 1000mIU/ml threshold) with pictorial instructions at 14d+standardized questions by telephone call with provider at 14d	Retrospective review of clinic database GA: ≤63 days 2% had GA = 64 d	LSUPT+ telephone call: 100% sensitivity, 88% specificity for on-going pregnancy.	LSUPT+ telephone call suitable alternative to in-clinic FU	LFT high although records checked for ongoing pregnancies. LTF leaving the area with ongoing pregnancies would not be identified

Ngoc et al. 2014 (95)	Multi-center Vietnam	N=1433, LTF~9%	Self-assessment vs. in-clinic provider PE and U/S	SQUPT and symptom checklist at 14d, +telephone call from provider vs. physical examination + U/S	RCT: RR for ongoing pregnancy, Feasibility and acceptability of self-assessment GA: ≤63 days	SQUPT+CL: 93% sensitivity, 91% specificity for on-going pregnancy. CL only: 71% sensitivity, 93% specificity. 97% SQUPT+CL easy to use. 88% preferred SQUPT+CL + telephone call if needed	SQUPT alone accurate, feasible, acceptable. With phone call to clinic, if needed to identify ongoing pregnancy.	Limited generalizability: 1 country, most had secondary education. Possible some on-going pregnancies went undetected for study if participants received care elsewhere
Gomperts et al. 2014 (96)	Out of facility Brazil	N=370, LTF~17%	Self-assessment, in some cases provider-assisted	Standardized internet form, or email correspondence with provider. Recommendations were UPT at 3 weeks or U/S at 10d	Service evaluation. MA outcome at various GAs	Outcome if MA aa GA<=7wks 19.3% additional surgery, higher at >13wks GA. 1.9% ongoing pregnancies at <=7 wks. GA	Home-use of the regimen of 200 mg oral mifepristone, 800 mcg misoprostol SL at 24 hours, repeat dose of 400mcg 4 hours later, safe and effective for MA through 12 weeks GA	All self-reported outcomes
Oppegaard et al. 2014 (97)	Multi-center Scandinavia	N=929, LTF~3%	Self-assessment out of clinic vs. in-clinic provider	Two step SQUPT (Veda lab, Duo 5 mIU/ml and 1000mIU/ml threshold) at 7-21d+ standardized question by telephone call at 28d vs. PE+U/S	RCT non-inferiority, (margin 5 percentage points): Complete MA within 3 months. GA: ≤63 days	Complete abortion in 95% of clinic vs 94% in self-assessment group. False neg. LSUPT result n=3. Symptom questions don't add accuracy	Self-assessment is non-inferior. This SQUPT needs improving	Insufficient recommendations offered on managing on false negative self-assessment
Cameron et al. 2015 (98)	Multi-center Scotland	N=1726	Self-assessment	LSUPT (Babycheck Duo, 1000mIU/ml threshold) with symptom CL + telephone consultation with provider if needed	Retrospective review of clinic database GA: ≤64 days	Self-assessment indicated risk of ongoing pregnancy: 6%. True ongoing pregnancy 0.4%, False negative self-assessment n=4	Unscheduled visits or telephone calls to the service are rare. Most but not all ongoing pregnancies are self-recognized early	Limited ability to fully verify all ongoing pregnancies

Iyengar et al. 2015 (99)	Multi-center India	N=731 LTF~4%	Self-assessment out of clinic vs. in-clinic provider	LSUPT (Vedalab, 1000mIU/ml threshold) with illustrated leaflet at 10-14d + illustrated symptom CL vs. PE+U/S	RCT non-inferiority, (margin 5 percentage points): Efficacy of MA + safety of MA and feasibility GA: ≤63 days	Complete abortion in 93% of clinic vs 95% in self-assessment group. 1 in each group had a blood transfusion.	Home assessment with a LSUPT feasible and effective in low income setting	Validation of test results not clear: Results suggest 1 false negative test.
Paul et al. 2015 (100)	Multi-center India	N=731, LTF~15%	Self-assessment out of clinic vs. in-clinic provider	LSUPT (Vedalab, 1000mIU/ml threshold) with illustrated leaflet at 10-14d + illustrated symptom CL vs. PE+U/S	RCT non-inferiority, acceptability of home-assessment GA: ≤63 days	FU modality: 57% overall preferred home-assessment to in-clinic. 82% in home-assessment group preferred home assessment	Home assessment highly acceptable in low-resource rural settings	Bias due to differential LTF between groups and information bias may be present
Platais et al. 2015 (101)	Multi-center Moldova Uzbekistan	N=2400, LTF~0,4%	Provider-assisted self-assessment; out of clinic vs. in-clinic provider	SQUPT (dBest hCG Panel Test; Ameritek, Seattle, WA, USA) with symptom CL + telephone FU with provider at 14d vs. PE+U/S	RCT: remote vs in-clinic provider: Ongoing pregnancy rate, (RR) acceptability and feasibility GA: ≤63 days	100% sensitivity, 97.5% specificity for on-going pregnancy. 94-95% found CL or PT easy to use. 76% prefer remote FU	Remote FU with SQUPT + CL + telephone call highly effective for identifying ongoing pregnancies	Underpowered for detecting ongoing pregnancy, not all abortion outcomes verified. Most had completed secondary school
Dunn et al. 2015 (102)	2 centers Canada	N=129, LTF~9%	Laboratory and provider-assisted assessment out of clinic vs. in-clinic provider	Serum β-hCG and symptom Cl + telephone call by provider at 15d vs. PE+U/S	Service evaluation of adherence to follow-up protocol. GA: ≤63 days	Adherence to follow-up protocol same for both groups, preference for remote FU, no associations with adherence.	Women should be offered choice for remote or in-clinic FU as similar safety profiles for both	Medication regimen was methotrexate with misoprostol - not generalizable Mifepristone regimens
Hassoun et al, 2015 (103)	Multi-center France	N=322, LTF=13%	Self-assessment out of clinic vs. laboratory + provider assisted in some cases	Two step SQUPT (Veda lab, Duo 5 mIU/ml and 1000mIU/ml threshold) at 14-21d+ illustrated leaflet at 14-21d	Prospective Concordance of LSUPT and serum hCG for ongoing pregnancy or incomplete abortion. Feasibility and acceptability GA: ≤63 days	Concordance same day (±1 day) 94.5%. Discrepancies: 2 incomplete abortions but no ongoing pregnancies. Women's interpretation of LSUPT correct: 90%. Test easy to read: 89%. FU method alarming or unsettling or both 17%	LSUPT sufficiently accurate, safe and relevant for women to monitor MA outcome	Not powered for full validation LSUPT of ongoing pregnancy or to determine associations with negative responses for FU modality.

Blum et al, 2016 (104)	2 centers Vietnam	N=600, LTF~3%	Self-assessment out of clinic vs. in-clinic provider	MLUPT (dBest hCG Panel Test; Ameritek, Seattle, WA, USA) vs. HSUPT vs. provider at 3d, 7d, & 14d vs. PE+U/S	RCT: MLUPT vs. HSUPT for abortion outcome	At 14 days: MLUPT + HSUPT 100% Specificity : MLUPT: 97% HSUPT: 62%	MLPT self-assessment is more reliable than HSPT, can be done 3 days after mifepristone	Miso administered 24hr after mifepristone and test days counted after mifepristone administration. Selection bias towards <49d GA
Dabash et al, 2016 (105)	Multi center Tunisia	N=404 LTF= 15%	Self-assessment out of clinic vs. in-clinic provider	MLUPT (dBest hCG Panel Test; Ameritek, Seattle, WA, USA) with illustrated leaflet at 14d vs. PE+U/S	Prospective trial. MLUPT vs in-clinic provider: Efficacy and acceptability and feasibility GA: ≤70 days	For GA <63d NPV 100%, Sensitivity 100% for ongoing pregnancies For GA 64-70d NPV 96.9% , Sensitivity 50% for ongoing pregnancies	Self-administered MLUPT accurate and easy to do for MA at <=63d GA Additional research needed on accuracy at 64-70d GA	Feasibility tested in research setting rather than true implementation setting. Underpowered for the subgroup 64-70days GA

The proportion of women not returning for in-clinic follow-up increased as MA became more widely available and better known (88). In response, researchers explored new approaches, including standardized symptom checklists in order to improve generalizability of results, and to develop a standard set of questions that might be used by non-clinical personnel to conduct phone-based follow-up (89, 92).

While the provider-assisted MA evaluation using symptom checklists was a step towards simplifying MA provision, in other settings, such as South Africa, this was not considered practical for the new MA service. Given this constraint, Study 2 of this thesis, was conceived in 2010 and conducted in 2011-2012. The study explored the feasibility of offering self-assessment to women on their mobile phones using an automated interactive questionnaire delivered via Unstructured Supplementary Service Data (USSD) technology. USSD is used to send text between a mobile phone and an application program, and at the time of the study incurred a user-cost of ZAR 0.2 per 20 seconds (26). Published studies appearing after Study 2 was underway indicated that self-assessment without provider guidance and based on symptoms alone is not sufficiently accurate to be recommended (88, 89).

Semi-quantitative urine pregnancy tests (SQUPTs), recently renamed as multi-level urine pregnancy tests (MLUPTs), and low sensitivity urine pregnancy tests (LSUPTs) have been extensively investigated in the recent past as the most promising modalities for safe and effective remote follow-up after MA (Table 2.1, studies from 2012-2016). The MLUPT is a five-level test, with thresholds for ranges of urine hCG for at least 25, 100, 500, 2000 and 10,000 mIU/mL (90, 93, 95, 101). The test allows for urine hCG levels following MA to be compared to baseline levels, measured prior to first MA medication. Accuracy, feasibility and acceptability of the MLUPT have been assessed and reported from the US, Vietnam, Moldova and Uzbekistan and most recently from Tunisia (90, 93, 95, 101,105). These studies report the MLUPT as highly sensitive in detecting ongoing pregnancies - only two undetected ongoing pregnancies were reported over all studies (95, 105). However, the MLUPT is not currently commercially available outside of the US and Kazakhstan, and could only be feasible in LMICs if offered at low cost, as monitoring change in hCG levels requires 2 tests to be performed (before and after) (95).

Low sensitivity urine pregnancy tests (LSUPTs) with thresholds of 1000mIU/mL or 2000mIU/mL and performed at 10-14 days after mifepristone, are cheaper and simpler to use, have been commercially available since 2010 and have been incorporated into clinic service delivery protocols in UK clinic settings (31, 91, 94, 98). Although highly accurate, studies suggest that the LSUPT performs less well than the MLUPT to detect ongoing pregnancies. In the UK, women choosing the LSUPT over in-clinic follow-up are required to sign a standard form stating they would make a return clinic visit if they experience scant bleeding, positive LSUPTs and persistent symptoms of pregnancy (98).

Subsequent well designed non-inferiority RCTs have reported accuracy, feasibility and acceptability of LSUPTS combined with checklists in other settings as diverse as Scandinavia (97) and India (99). Modification of accompanying instructions with illustrations was done to allow for illiterate women unable to read instructions in the India study (99). Both these studies have limitations in that there is a chance some ongoing pregnancies were missed. In addition, the LSUPT did not detect the three ongoing pregnancies recorded in the Scandinavian study (97).

In the South African setting prompt recognition of ongoing pregnancy is particularly important as most women eligible for MA are close to the GA limit of 63 days (Unpublished service statistics). In this context, access to MVA and second trimester D&E services is uneven and these services are frequently overbooked (107). Since all studies using the LSUPT (97, 98) reported that women with initial false negative LSUPTs received their abortion, although delayed, it was decided by the candidate to explore the use of the LSUPT rather than the more complicated MLUPT in the South African setting (Study 3), with the aim of strengthening and simplifying MA service provision and providing a suitable and affordable option for early recognition of ongoing pregnancy.

2.7 Medical abortion in the second trimester

2.7.1 Search Terms

Literature search terms used alone and in combination for this section included “acceptability”, “effectiveness”, “efficacy”, “second trimester”, “mid trimester”, “medical abortion”, “abortion”, “eligibility”, “misoprostol” and “mifepristone”.

2.7.2 Introduction

Abortion in the second trimester is associated with more medical risk than first trimester procedures (9, 108, 109). Higher overall dosages of misoprostol are needed to complete the abortion and the misoprostol should be administered in an in-patient hospital setting (6, 110). If placental tissue is retained after successful expulsion of the fetus, a surgical procedure may be needed. The final section of this chapter appraises the published literature on methods used in second trimester abortion, medication regimens, as well as rates of minor and major complications. Challenges in introducing second trimester medical abortion services in other LMIC settings are described and options for task sharing and self-management are identified.

2.7.3 Methods for second trimester abortion

There are limited studies comparing dilatation and evacuation (D&E) (second trimester surgical method) to medical induction (MI) (second trimester medical method) in terms of efficacy, safety and acceptability; they are mostly from developed country contexts (111-114), but include an observational study from the Western Cape, South Africa (107). These studies confirm the WHO recommendation of D&E as the most efficient method, if available (115). However, there are limited options in South Africa for expansion of D&E, and this service is mainly outsourced to private doctors. In the public sector D&E is provided only in the Western Cape (personal communication, D&E provider for NGO; Feb 2016). If no D&E service is available, the WHO-recommended regimen is a combination of mifepristone followed by a prostaglandin analogue (115).

In the absence of mifepristone, prostaglandin analogues such as misoprostol alone can be used (115), as is the case in public sector facilities in South Africa, with the exception of the Western Cape, where mifepristone was introduced in late 2013. Misoprostol-only medical abortion as provided in the Western Cape in 2008/2009 was documented to be provided safely, with few major complications. Areas that were identified for improvement were the long delays between first seeking care and receiving the abortion, which, coupled with prolonged hospital stays, resulted in a shortage of available hospital beds and limited access (107). The study motivated for the introduction of mifepristone in combination with misoprostol as a means of addressing these problems. If, as expected from published trials,

introducing mifepristone into second trimester medical abortion services could improve access and reduced delays, it was proposed that a model of second trimester medical abortion care could be developed for the rest of the country and for other LMIC countries developing programs for later medical abortion care (107). Providers of second trimester abortion care were in agreement that introducing mifepristone would help strengthen provision of second trimester medical abortion (109).

2.7.4 Evidence-base and guidelines for second trimester medical abortion

Approval for mifepristone use in the second trimester has generally followed approval for first trimester MA with some delay, and was in place in China, the UK and numbers of European countries by early 2000 (116). Clinical studies from the UK reporting improved efficacy using mifepristone combined with prostaglandin analogues were reported as early as 1992 (117). By 1997, Royal College of Obstetricians and Gynaecologists (RCOG) guidelines recommended mifepristone before administration of a prostaglandin analogue as safe and effective for second trimester MA, basing this recommendation on level B evidence (118). This guideline also cited the publication showing the lower 200mg mifepristone dose to be as effective for second trimester MA as the higher 600mg dose (119). Subsequent RCTs aimed to strengthen the recommendation, and generate evidence for improved efficacy using variations in misoprostol timing and administration route, following pre-treatment with the lower 200mg mifepristone dose. Current guidance for clinical management from various professional bodies (11, 115, 120) (Recommendation 7.23) recommends 200mg mifepristone (oral) followed by repeated doses of misoprostol administered vaginally, then sublingually, as the most effective medication regimen. While these guidelines are supported by many case series and non-RCTs, they cite only two RCTs that compared efficacy for mifepristone-misoprostol to misoprostol alone, using the same misoprostol regimen in both study arms. (12, 121). Both RCTs demonstrated higher success rates and shorter times-to-abortion for the combined medication regimen. The median times-to-fetal expulsion for those receiving mifepristone were 10 hours (range 8-12) (121) and 7.3 hours (range: 2.5 – 14.8). The 24- and 15-hour abortion rates were 97% and 86% respectively, significantly higher than the misoprostol-alone groups. These studies are also considered the only appropriate designs evaluating effectiveness of adding mifepristone to misoprostol in a Cochrane systematic review (122). More recently a RCT conducted in Tunisia with 120

participants (GA 14-21 weeks) (123), used a protocol similar to that of Ngoc et al. (12), but extended misoprostol dosing beyond 24 hours, to establish whether differences between the two regimens continued among those experiencing delays to completion. The 24-hour completion rate was 88% for the mifepristone group (vs. 48%, misoprostol alone). The higher success rate for the misoprostol group was also significant at 48-hours (123).

2.7.5 Confounding factors for efficacy of the mifepristone misoprostol regimen

The efficacy of medication regimens is confounded by confounding user-related factors, which must be borne in mind when reporting the clinical outcomes and caring for women. For the mifepristone-misoprostol regimen, gestational age, parity, prior vaginal delivery and age are potential confounders of time-to-abortion, but with inconsistent results across studies. Generally, time-to-abortion has been shown to increase with gestational age over the range of 12 – 20 weeks (124-126), although this is variable (12, 121, 123, 127), perhaps due to an increase in sensitivity of the uterus to prostaglandins at later GAs (128). In most studies, nulliparity or no prior vaginal delivery has been significantly associated with increased time-to-abortion (123-126, 129, 130), while age seems relatively unimportant (12, 121, 123, 124, 127).

2.7.6 Misoprostol regimens

Shortening the dosing interval between mifepristone and misoprostol allows for a trade-off between efficacy and duration of the procedure overall (from time of mifepristone administration) for the woman. Various service delivery options in this regard can be implemented to best suit both women and service providers. The 36- to 48-hour interval results in significantly shorter time from misoprostol to abortion completion (125, 127, 129, 131, 132) compared to a 24-hour interval or to immediate dosing (133). However, the clinical or practical significance of the 1-2 hour difference is limited (132). Flexibility in dosing interval has great potential to accommodate the needs of both women and service providers, and incorporating this into service provision can be recommended.

RCTs have explored how best to balance efficacy against side effects for high dosages of misoprostol (122). Based on these studies, the WHO recommended vaginal (PV) administration, although the sublingual route is similar in multiparous women. The oral route is least effective, and accompanied by more vomiting than vaginal or sublingual

administration. As the induction process progresses PV misoprostol may be disturbed due to vaginal bleeding, and may be substituted with sublingual or buccal administration (122). In terms of dosing intervals, three-hourly dosing of misoprostol is recommended above six-hourly (122).

2.7.7 Uterine evacuation with curettage following fetal expulsion

Routine curettage for retained placental tissue following fetal expulsion is standard care in some settings (134). Where this is discretionary, rates can vary substantially within country settings (between 16% and 87%, (135), and according to study design end-points (12). However, large case series suggest that <10% might be expected if curettage is not routinely performed (124, 126, 130). Curettage, if not medically indicated, is wasteful of hospital resources and both clinician's and women's time, and routine curettage constitutes a paradoxical approach if programs are aiming to improve access, efficiency and acceptability of second trimester medical abortion services (135).

2.7.8 Mifepristone in other low-and middle income settings

Research has been conducted on the safety and efficacy of mifepristone-misoprostol regimens in low- and middle-income settings including Vietnam, Tunisia (12, 124, 126, 130), China (127, 129) and India (136, 137). In addition, broad-based, comprehensive initiatives supported by NGOs to introduce MI services with mifepristone-misoprostol regimens have shown promising results in Nepal, Mongolia and Ethiopia (138-141). Key lessons learnt were the need to involve policy makers, OBGYNS, and other stakeholders to sustain initial efforts in setting up services (141). South Africa also benefitted from substantial support from NGOs and other organizations for training and roll-out of services in general, including D&E (142). However, twenty years after the CTOPA, access to second trimester services in the public sector appears to have shrunk (Personal communication, NGO Country Director; May, 2015).

Introducing mifepristone misoprostol regimens for second trimester in LMICs is not without challenges. Lack of available beds, questions around sustainability of services and reliable supply of medication, and inadequate monitoring and evaluation of programs are some of the problems that have been reported from such settings (107, 138, 139, 141).

2.7.9 Self-management and task sharing in second trimester medical abortion

Hospital admission with access to specialist services is a safety requirement in many countries including South Africa for MA in the second trimester (6), and WHO guidelines recommend that women remain under observation until abortion completion is confirmed either by specialist or non-specialist doctors (7). For these reasons, opportunities for self-management are limited. However, if mifepristone is self-administered at home at an agreed-upon time, and a flexible dosing interval is applied when appropriate, both service providers' and women's needs in terms of travel distance, and managing work and family demands can be served. Thus, in Vietnam, mifepristone was self-administered at home; 1/260 women did not return for admission, although it was unknown if the mifepristone was taken in this case (12). Off-site self-administration of mifepristone is currently a topic of research for MA in the first trimester - US-based studies confirm this to be highly acceptable, convenient and safe (143, 144), and reinforce the advantages of self-management in medical abortion provision. In addition, where facilities have readily accessible surgical back-up and infrastructure to manage complications, the task of monitoring and caring for women from first misoprostol administration to completion of the abortion is frequently performed by nurses or midwives, rather than by specialist or non-specialist doctors (7).

2.8 Conclusions

This chapter synthesized and appraised the published literature on ways to simplify service delivery, expand access and strengthen quality of MA provision following the introduction of mifepristone into abortion care. The literature shows that developments in clinical and in research settings have gained momentum in recent years, both in developed and developing countries. To this end, researchers have explored the potential for task sharing as a strategy that may best serve women's needs and address provider shortages. This review separately appraised the evidence for strengthening task sharing each subtask in early MA, and then for strengthening second trimester MA provision. The findings of the review have shaped the objectives, and the development and evaluations of the interventions that constitute the empirical research performed in this thesis.

Research from a range of settings has shown that gestational age estimation from LMP among women seeking abortion is mostly, but not fully accurate, and can safely replace ultrasound or bimanual examination for MA GA eligibility for most, but not for all women. Evidence from South Africa indicated there could be some concerns with respect to the accuracy of LMP recall. Chapter 3 will aim to establish criteria for safe use of LMP-based gestational dating, and will explore providers and CHWs perspectives on sharing this subtask in the South African context.

Increasingly, and in many different settings, self-administration of misoprostol and off-site self-management of early MA has become acceptable to most women and providers. Where this is standard care, women need careful counselling by providers to address their concerns and the experience of self-managed MA is much improved if additional support is available during the MA process. As many women may not have this support, and written material in clinics are not well-utilized, scope exists for evaluating other ways of providing support and reassurance for women. The research in Chapter 4 will evaluate the use of mobile phone technology in this regard, and evaluate effectiveness and acceptability of this modality in the South African setting.

Failure or complications are rare events in MA up to 63 – 70 days GA, and the follow-up clinic visit is burdensome and unnecessary for most women. Research on simple and accurate tools for self-assessment has evolved and has been reported from numbers of countries, but only introduced to a limited extent into clinic settings. There is no published evidence for the South African setting, and the interventions researched in Chapters 5 and 6 aim to address this need.

Second trimester abortion provision can be greatly improved by introducing mifepristone, however this has not been implemented in many LMICs where early MA is available. Task sharing can involve off-site self-administration of mifepristone and monitoring and caring by nurses during the hospital stay. Outcomes following the introduction of this regimen into the Western Cape second trimester medical abortion services will be reported in Chapter 7.

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Chapter 3

3.1 Paper 1. Accuracy of gestational age estimation from last menstrual period among women seeking abortion in South Africa, with a view to task sharing: a mixed methods study

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Paper overview

This study evaluated the accuracy of gestational age (GA) estimation using last menstrual period (LMP) among women seeking abortion, and explored providers' and community health workers' (CHWs) perspectives on task sharing this activity. The study was a multi-site cross-sectional study conducted at four urban non-governmental reproductive health clinics in South Africa. GA from LMP recorded by CHWs was compared to GA by ultrasound (U/S) performed by clinicians. Sub-group analyses were done to identify criteria that would allow for a safe self-managed medical abortion if GA eligibility was based on LMP dating. In-depth interviews were conducted with six providers and seven CHWs to gauge their support for this approach.

Contribution to this thesis

This study addressed question 1 of this thesis: is it safe and acceptable to replace the ultrasound gestational age assessment for first trimester medical abortion with last menstrual period dating determined by community health workers?

The novel contribution of this study lies in the context-specific findings. In this study, 3% of women reporting an LMP date within 56 days had ultrasound GAs >70 days. Although a small percentage, compared to other settings, this result suggests that some additional risk management may be needed if task sharing of LMP-based GA estimation is implemented. Perspectives of health-care workers have similarities to other contexts with respect to task sharing, but appear to be influenced by local factors.

Role of the candidate

A parent multi-country study was conceived and designed by a broader research team from the WHO and by Dr. Harries from UCT. The candidate was responsible for managing the data on the parent study and was a co-author on that publication. The candidate was solely responsible for conceptualizing and conducting the analysis for Study 1 (this thesis) presented below. The candidate drafted, and finalized the resulting manuscript for submission and is the lead and corresponding author.

3.2 Introduction

Abortion on request in the first trimester of pregnancy was made legal in South Africa in 1997, and mifepristone for medical abortion (MA) was approved in the Western Cape for use in the public sector up to 63 days gestational age (GA) in 2010 (1). MA has gradually been introduced into primary care public sector health facilities around the country since 2011, however expansion of the service has been slow, in part due to a scarcity of trained providers, and rural districts are generally underserved (2). In the Western Cape access has been limited to facilities or referral centers that have ultrasound (U/S) equipment and the requisite expertise as the 2010 Western Cape MA guidelines (1) mandated the use of U/S to determine GA eligibility for all abortion procedures – in contrast to other more recent recommendations where routine use of pre-abortion U/S is considered unnecessary (3) and has been replaced with bimanual clinical examination (4). However, if GA based on last menstrual period (LMP) can be accurately assessed by community health care workers (CHWs) in supportive roles, or self-assessed by women themselves, this could potentially reduce delays, improve access and save providers' time.

The requirement for an U/S examination is a barrier to abortion access in many resource-limited settings and researchers have long challenged this prerequisite (5-7). More recently the accuracy of LMP based GA has again been under review (8) with efforts to identify criteria that would ensure a safe and effective MA in terms of a woman's GA, using LMP rather than U/S (9). An earlier study from South Africa found that LMP-based GA was accurate on average, compared to ultrasound dating, but that there were high levels of uncertainty among 12% of women (6). Other published studies demonstrated better accuracy of LMP-based GA estimations (9), suggesting that LMP recall may vary according to country context (5, 7, 9, 10). It is also evident that LMP recall is more difficult for women with irregular menstrual cycles (11) and that recall can be significantly biased among women seeking abortion when the pregnancy is advanced (12).

To expand access to MA where barriers exist due to the U/S requirement and provider shortages, the most recent WHO guidelines (13) recommend task-shifting LMP-based GA estimation to lay health workers or for women to evaluate this themselves, but these

guidelines caution that further rigorous contextual research is needed. Similar recommendations were made with respect to self-assessment of GA for MA eligibility by women themselves (13).

This study analyzes data from a larger multi-country validation study of a MA eligibility checklist tool for use by CHWS (14). In this sub-study we compare three methods of GA estimation: 1) LMP plus calculation by investigators of intervening days for GA estimation, 2) LMP plus pregnancy wheel used by CHWS for GA estimation, and 3) GA from ultrasound examination by clinicians. In addition, we describe providers' and CHWs' perspectives on task sharing eligibility assessment for MA. The purpose of the study is to advance the potential for GA eligibility for MA to be performed by CHWs or by women themselves, without the need for ultrasound examination, in order to expand access to MA services in South Africa.

3.3 Materials and methods:

3.3.1 Study participants and setting

Women were recruited between August and November, 2012 in urban sexual and reproductive health clinics providing abortion in Kwazulu-Natal (three clinics) and the Western Cape (one clinic). The sample size calculated for the parent study was based on the assumption that 60% of women seeking abortion would be eligible for MA. To achieve two-sided 90% confidence interval for 60% ±15% sensitivity and 80% ±15% specificity, it was estimated a sample size of 211 was needed (14). The project was conducted at non-governmental organization (NGO) clinics with providers (nurse clinicians) trained in medical abortion as well as certified CHWs in counselling roles; at the time no public sector service was able to meet these requirements. For this study, CHWs received two days of didactic training on the menstrual cycle, abortion methods and eligibility, and use of the pregnancy wheel.

3.3.2 Study procedures

3.3.3 Gestational age assessments

Women seeking abortion at study clinics were approached by a research assistant to determine interest and eligibility. Eligibility criteria were: 18 years or older, able to speak local languages, and willing and able to give written informed consent. Eligible women

provided written consent, completed a socio-demographic questionnaire with the research assistant, and were interviewed by CHWs using the medical abortion assessment toolkit developed for the parent study. CHWs recorded known or estimated LMP with the aid of a calendar when needed, used the pregnancy wheel to establish eligibility for medical abortion based on GA, and recorded the GA from the wheel if within 63 days. Thereafter women were seen by a provider who completed a standard clinical examination protocol including an ultrasound examination for eligibility for medical abortion and recorded these data. None of the women had been informed of their GA prior to joining the study, and the CHWs were masked as they interviewed women prior to them seeing the clinician.

The main outcome was the difference between LMP-based GA estimates compared to US-based GA. Two methods of LMP-based GA were included in this analysis; firstly, from CHW's estimate of GA using the pregnancy wheel (only recorded where wheel GA was within 63 days - referred to as *GA by wheel*), and secondly, by investigator post-hoc calculation of GA based on recorded LMP date (referred to as *GA by calculation*) for all participants. Mean LMP-based GA estimations were compared to U/S GA using paired t-tests and Bland Altman plots. For each of the LMP-based methods we calculated the proportion of cases in the caution zone, described as those with an LMP-based GA within 63 days, but with U/S GA beyond 63 days (5). Conflicting classifications of cases into the caution zone using the pregnancy wheel compared to the digital calculation were identified and described. Potential associations for being in the caution zone and for being unsure of LMP date were assessed using Kruskal-Wallis and Chi-squared tests for continuous and categorical variables respectively. Following the approach in recently published literature (9), we then calculated the proportion of women whose GA *by calculation* was either <=56 or <=63 days but for whom U/S GA was beyond 63 days or 70 days. Subgroups in this analysis included women who stated they were sure of their LMP date.

3.3.4 In-depth interviews

In-depth interviews (IDIs) were done with all CHWs and providers who had assessed at least six women in the quantitative study when data collection for gestational age assessment was complete. Following informed consent, interviews were conducted by an experienced study investigator in English, according to a semi-structured interview guide. IDIs were

recorded and transcribed, and stripped of personal identifiers. Transcripts were analyzed using a thematic approach based on the interview guide.

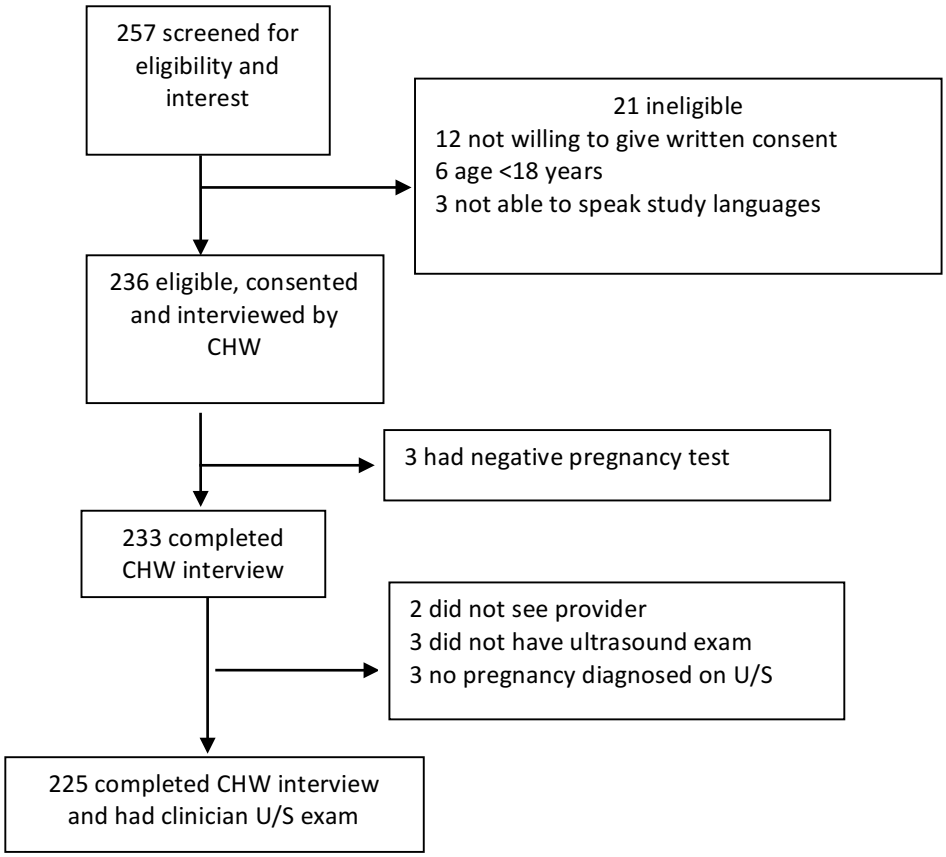
All participants in the study provided written informed consent and confidentiality and anonymity were safeguarded. Women received ZAR50 reimbursement on conclusion of their participation in the study for any expenses incurred; providers and CHWs were not reimbursed for participating in the IDIs. The study protocol was approved by the World Health Organization Research Ethics Review Committee and the University of Cape Town's Human Research Ethics Committee.

3.4 Results

3.4.1 Gestational age assessments

Between August and October 2012, 236 women were enrolled. Of these, eleven were excluded from this analysis (Fig. 3.1) leaving 225 pairs with complete data; three had a negative pregnancy test according to the CHW, two did not see the clinician, three did not have pregnancies confirmed by ultrasound, and three did not have an ultrasound examination due to disruptions in clinic routines.

Figure 3.1 Flow chart of participants enrolled into the study



There were 94 participants from the Western Cape and 131 from KwaZulu-Natal (Table 3.1). Significant differences in demographic or reproductive characteristics between the two regions included a higher percentage of women from the Western Cape with prior abortions, with paid work, who used a contraceptive method in the past year and who were not sure of their LMP as recorded by the CHW.

Table 3.1 Study participant sociodemographic and reproductive characteristics

	Western Cape (n=94)	**Kwazulu/Natal (n=131)**	**Total (n=225)**	**p-value***
Age, (years) Median (IQR)	26 (23.0-31.3)	26 (23.2-29.3)	26.0 (23.0-30.0)	0.452
School education, (years) Median (IQR)	12 (11-12)	12 (11-12)	12.0 (11.0-12.0)	0.823
Paid employment (Yes) n (%)	63 (67.0)	31 (33.0)	94 (40.9)	<0.001
Previous pregnancies, n (%)				0.868
0	20 (21.3)	31 (23.7)	51 (22.7)	
1	30 (31.9)	43(32.8)	73 (32.4)	
2+	44 (46.8)	57 (43.5)	101 (44.9)	
Prior abortion (among those ever pregnant) n (%)	21/74 (27.3)	10/100 (10.0)	31/17 (17.2)	0.003
Used contraception in last year (Yes) n(%)	78 (83.0)	60 (45.8)	138 (61.3)	<0.001
Sure of LMP date (Yes) n (%)	73/94 (77.7)	121/131 (92.4)	194/225 (86.2)	0.002

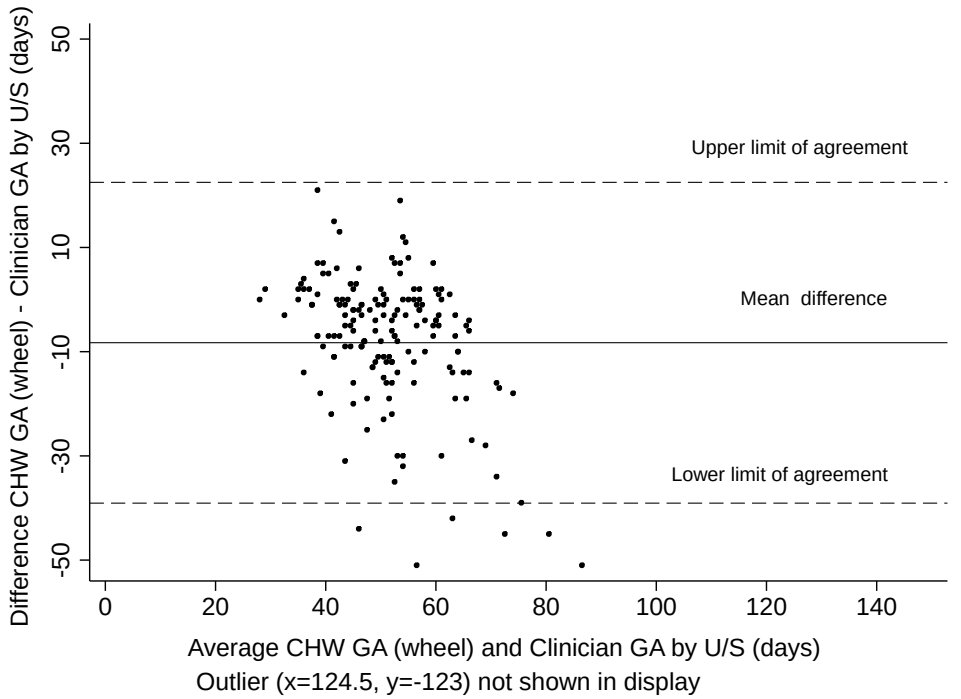
* Chi-squared tests for comparing categories, Kruskal-Wallis test for comparing medians.

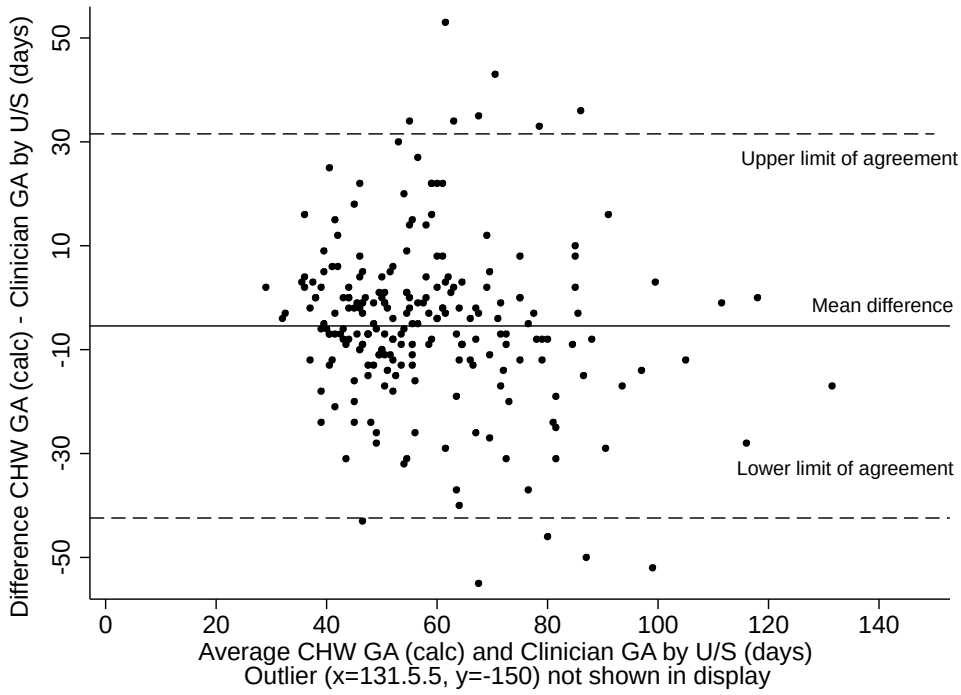
CHWs established known or estimated LMP date for all 225 participants. Using the pregnancy wheel, GA was within 63 days and was recorded by the CHW for 170/225 (76%), and GA from LMP was calculated for all 225 participants, which included those with later gestations. Mean LMP-based GA *by wheel* for the subset of 170 participants (47 days, SD=9.3) was nine days shorter than GA by U/S (56 days, SD=17.2 p<0.001) and for all participants, mean LMP-based GA *by calculation* (56 days, SD=17.7days;) was five days shorter than GA by U/S (61 days, SD=21.3; p<0.001).

Bland-Altman plots illustrating the difference between LMP GA and U/S GA against average GA are shown in Fig. 3.2. The limits of agreement (GA *by wheel* = -39 to 22 days; GA *by*

calculation = -42 to 31 days) were wide for both methods. The plots demonstrate increasing underestimation using LMP GA as the pregnancy progresses, which was more prominent for GA *by wheel* than for GA *by calculation*.

Figure 3.2 Bland Altman plots comparing LMP-based GA with U/S GA





LMP GA *by wheel* allocated 31/170 (18%) and GA *by calculation* allocated 28/225 (12%) to the caution zone. Where there was conflicting classification into the caution zone by GA *by wheel* compared to GA *by calculation*, four cases were underestimated by three to six days and once case by 30 days using the wheel compared to the calculation. In contrast, two cases were overestimated using the wheel and classified as ineligible so not in the caution zone, but were eligible according to calculation from LMP. Further analysis of the caution zone using the LMP GA *by calculation* results showed that most (22/28; 79%) had GAs between 9-12 weeks. Of the six cases with a GA >12 weeks, three were unsure of their LMP, all had prior pregnancies, and none spoke English as their home language (English home language was uncommon among all participants; 31/225, 13.8%).

The only significant association with being in the caution zone was uncertainty of LMP date. Three participants did not know their LMP date, while 28 were unsure of this date. Combining "not sure" and "don't know", the association with being in the caution zone was significant for GA *by wheel* ($p < 0.001$), and for GA *by calculation* ($p = 0.015$). By definition, women with later U/S GA were more likely to be in the caution zone. No significant associations with being in the caution zone were found for age, home language, employment status, marital status, numbers of previous pregnancies or any previous abortions, use of any contraceptive method in the past year, use of an injectable contraceptive in the last year; nor were there any significant associations by province, community health worker or by clinician. There were no significant associations with being unsure of LMP other than increasing gestational age ($p=0.035$).

From these findings, of the women estimating their LMP to be within 63 days, 18% and 11% would have received a MA at U/S GAs of >63 days and >70 days respectively, (Table 3.2). For those sure of their LMP, this would have been 14% and 8%. However, of the women reporting LMP dates within 56 days, 10% and 6% would have received a MA at U/S GAs of >63 days and >70 days and for those sure of their LMP, this proportion decreased to 7% and 3%. Among the 3%, all had U/S GAs beyond 75 and within 84 days.

Table 3.2 Proportion of women with U/S GA beyond 63 or 70 days according to subgroups of LMP-based GA, <=63 days and <=56 days

Gestational age	All participants	Participants "sure" of LMP
N with LMP and U/S GA recorded	225	194
n (%) GA ≤ 63 days by U/S	152 (67.6)	140 (72.2)
n (%) GA ≤ 70 days by U/S	169 (75.1)	152 (78.4)
N with GA ≤ 63 days by LMP	159	143
n (%) GA ≤ 63 days by U/S	131 (82.4)	123 (86.0)
n (%) GA ≤ 70 days by U/S	142 (89.3)	132 (92.3)
N with GA ≤ 56 days by LMP	128	118
n (%) GA ≤ 63 days by U/S	115 (89.8)	110 (93.2)
n (%) GA ≤ 70 days by U/S	120 (93.8)	114 (96.6)

3.4.2 In depth interviews

We conducted interviews with six of the ten providers (3 completed <6 assessments, 1 was unavailable) and seven of the eight CHWs (1 completed only 3 assessments). All four clinics were represented. On average, providers were 29 years (SD: 7 years) and CHWs were 40 years old (SD: 15 years). There was one male provider and one male CHW, all had completed their high school education. Providers had between two and ten years' experience and CHWs between ten months and three years' experience working in the health sector.

3.4.3 Acceptability of task sharing MA eligibility assessment

Providers were supportive of the notion of task sharing assessment of women's eligibility for MA, but saw this process as a preliminary screening prior to referral to the clinician for a clinical assessment. They saw the role of CHWs as confined to counselling and providing information on the abortion procedure as they believed women did not accurately report their LMP dates. In addition, they felt problems could arise if there were conflicts between CHW's and clinician's estimates of GA and eligibility for an abortion.

"Ultimately a professional clinician should assess gestational age" (Centre manager, NGO).

CHWs were generally positive about their role in assessing eligibility for MA. They were in agreement with providers that women were inaccurate with their LMP dates, but had a number of suggestions for ways of helping women recalling their LMP more accurately. Some CHWs felt reassured that a clinical exam would still be performed after their assessment, particularly for women who experienced menstrual irregularity. CHWs were familiar with pregnancy tests, easily followed the questions on the study form, a few found the pregnancy wheel problematic initially, although competency improved with practice.

3.4.4 Implementing task sharing of MA eligibility assessment

There were discrepancies between providers and CHWs and lack of agreement on a service delivery model for implementation of task sharing. Providers expressed some concerns about lack of supervision and accountability for CHWs, and that CHWs might provide information outside their scope of practice. In contrast, CHWs were enthusiastic about expanding their skills and area of practice.

Providers felt it would be most beneficial for CHWS to proactively do eligibility assessment and provide information within the community, while preserving confidentiality, rather than at the clinic. However, CHWs felt the clinic was a better place for this due to lack of privacy in their usual encounters with community which were either group discussions or home visits. Ideas for alternative placements for CHWS to conduct assessment and provide information included government clinics, hospitals and universities, while schools and homes were not considered advisable due to stigma around abortion and confidentiality concerns. Individual assessment and referral could be done telephonically or in a private place following a group information session.

3.5 Discussion

This clinic-based study compared LMP-based GA to an ultrasound exam to determine the potential for screening GA eligibility for MA by CHWs or by women themselves using LMP recall. The study found that on average, differences were slightly larger than other studies in which clinicians use LMP date to estimate GA among women seeking abortion (5, 6, 8). Use of the pregnancy wheel contributed to error, with 7/31 (23%) misclassifications with respect to the caution zone using the pregnancy wheel compared to a calculation from LMP date.

The pregnancy wheel has been reported elsewhere as prone to inaccuracies and use of electronic pregnancy calculators is considered superior to manual calculations in clinical settings (15, 16). Recently, online electronic pregnancy calculators for mobile phones have become readily available, are accurate and easier for women and CHWs to use, with a pregnancy wheel for back-up and in settings where this is not feasible (17).

GA *by calculation* allocated 12% to the caution zone, which is similar to earlier studies conducted in the US and South Africa (5, 6). Uncertainty of LMP date was the only significant association with being in the caution zone in this study. While little conclusive evidence has been published on predictors for being in the caution zone (5, 6, 12), being unemployed, primigravidity, pregnancy denial and failure to recognize pregnancy signs have been associated with inaccuracies in estimation of pregnancy duration (5, 18).

Of importance is the proportion of women who would be classified as eligible for MA according to their LMP but whose U/S GA is beyond the safety and efficacy limits for MA. Recent research (19-22) has demonstrated that 200mg mifepristone combined with home-administered misoprostol is safe and effective for MA up to 70 days GA. In this study, only 3% of women who were sure that their LMP date was at least 56 days prior would have had a MA beyond this 70-day limit. This is more than the 0.6% for US women in 2011, but less than the earlier study (7.8%) of US women in 2000 (9). Currently in South Africa, MA with off-site use of misoprostol is permitted up 63 days GA, however extending the MA GA limit to 70 days and task sharing GA eligibility decisions to CHWs or to women themselves would result in a safe MA for most women who state that their LMP is within 56 days. For example, of 1000 women seeking abortion and giving an LMP date no longer than 56 days earlier: If assessed by a CHW, 970 would be managed safely and effectively and 30 might need an additional intervention such as an aspiration procedure.

Fourteen percent of women were uncertain or did not know their LMP date, as compared with the US (19%) and the UK (9.5%) (8). The association between certainty of LMP and accuracy of LMP date is be expected. For women who are unsure of their LMP, additional prompts could help women reach a close approximation. Irregular menses and absence of a

personal calendar record or any significant event such as a birthday, have been shown to hinder LMP recall (23).

The IDIs showed health care worker's concerns with respect to women's ability to accurately report their LMP. However, these concerns appear to be unwarranted for women who recall their LMP to be within 56 days, with a degree of certainty. Recognizing this, the recent guidelines for MA (Canada) state that ultrasound is not needed to determine GA eligibility where women are sure of their LMP (24). Recall is usually vaguer over longer periods of time and discrepancies between LMP based GA and U/S GA increase at later GAs (5, 9, 12, 18). In addition, a higher likelihood of underestimating GA among women seeking abortion compared to women planning to take the pregnancy to term has been reported (12). However, in this study CHWs did not often evaluate women in the second trimester as eligible for early MA – most women with advanced pregnancies were likely to be correctly identified as requiring referral to centers providing second trimester services.

As LMP for gestational age estimation is self-reported information, it may become commonplace for women to use an online pregnancy calculator based on LMP to self-assess whether they are eligible for MA. However, in settings where vacuum aspiration services are less accessible than MA services, screening and referral by CHWs, either community or facility-based, has potential as a service delivery model. Self-management or task sharing of GA assessment could relieve pressure from providers, and pave the way for increased access to MA particularly in under-resourced facilities where U/S is not available. For women not eligible for MA, providers skilled in bimanual pelvic examination can safely determine gestational age eligibility for first trimester abortions including MVA.

Study limitations included limited generalizability due to the selection of NGO health services for the study and that CHWs received specific training. We did not ask women whether they had regular menstrual cycles, which might be a significant factor determining accurate recall of LMP. Sustained and broad based implementation of task sharing would require careful planning, and provision of training and support and certification for CHWs. In addition, the concerns of providers with respect to their clinical domain need to be addressed during this process.

3.6 Conclusions

In South Africa, if GA calculated from women's recall of LMP is within 56 days, this would ensure a safe medical abortion is provided in most cases. If unsure of their LMP, and for those with further advanced pregnancies, women would be advised to seek more specialized services. If LMP is used for GA estimation without additional clinical confirmation, additional emphasis should be placed on signs of ongoing pregnancy and complications during counselling for women who will be will be self-administering misoprostol and managing their procedure off-site. If risks are well-managed, task sharing or self-assessment of GA from LMP could expand access and strengthen MA services at primary care level.

3.7 Acknowledgements

We thank our research assistants and community health workers for their efforts in recruitment and interviewing, as well as all participants in the study.

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Chapter 4

4.1 Paper 2. Mobile phone messages to provide support to women during the home phase of medical abortion in South Africa: a randomised controlled trial.

Constant D, de Tolly K, Harries J, Myer L.

Publication Status: Published in Contraception 2014; Sep;90(3)226-33

Paper overview

This paper evaluated whether automated text messages to women undergoing medical abortion effectively reduced anxiety and emotional discomfort, and whether synchronized messages better prepared women for symptoms they experience. The study was a multisite RCT comparing standard medical abortion care to standard care plus a messaging intervention. Emotional outcomes were evaluated using validated instruments including the Hospital Anxiety and Depression Scale, Adler's 12-item emotional scale and the Impact of Event Scale-Revised. Preparedness for the abortion symptoms and overall satisfaction with the procedure were assessed using 4-point Likert-type scales. Changes in anxiety and emotional state between baseline and follow-up and differences in stress and preparedness at follow-up were evaluated for the two study groups.

Contribution to this thesis

This paper addresses the second question of the thesis: Is an automated timed text message program an effective and acceptable mechanism to provide support to women who are self-managing medical abortion at home?

This was the first published RCT evaluating the use of timed, automated timed text messages to support women while self-managing their medical abortion at home. Findings showed that the intervention was effective in decreasing anxiety and emotional stress over this period. The intervention also significantly improved preparedness for the abortion experience. Acceptability and other negative emotions relating to the abortion were unchanged by the intervention. Most women would recommend the messages to a friend having the same procedure.

Role of the candidate

The candidate was responsible for conceptualization of the study and study design in collaboration with a technical co-investigator. The candidate also selected the evaluation tools, and managed all field activities throughout the project. The candidate was solely responsible for data management and this analysis. She drafted and finalized the manuscript and was the lead and corresponding author on the paper.

4.2 Introduction

Medical abortion (MA) services using mifepristone followed by misoprostol have expanded in South Africa as an intervention to increase access to abortion services. Compared to surgical methods, MA with home use of misoprostol is less burdensome for health care providers, as responsibility for managing symptoms after misoprostol ingestion is shifted to the woman without direct support from providers (1, 2). MA in the first trimester has been shown to be highly acceptable to women in South Africa and elsewhere (3, 4). MA acceptability is dependent primarily on the success of the procedure, and may be moderated by experiences of pain, side effects and access to support (4-7). Overall satisfaction and fewer adverse emotional reactions to the abortion have been associated with both the availability of psychosocial support and adequate preparation for expectations around the procedure (8-10). For women taking misoprostol at home, counselling and guidance by providers (8) and the positive effect of sympathetic and non-judgmental support systems (11) are important components of effective care.

The use of text messages on mobile phones to strengthen sexual and reproductive health services in low-and-middle-income countries has shown promising results (12-16), and is considered feasible in settings where coverage and penetration of mobile phones is extensive or increasing (14). As in many parts of the world, mobile phone usage is commonplace in South Africa, especially in urban areas (17, 18).

Remote support using the internet or telephone to inform, to support, and/or to assist women with assessment of their abortion, has been successful in other settings (19-22). To our knowledge, text messaging has not been used previously to offer guidance and information for women managing their abortion symptoms at home. This research examined whether timed, automated text messages delivered between clinic visits for mifepristone and follow-up of MA could provide support and guidance in 'real time' to women. Specifically, we hypothesized that a series of text messages could reduce anxiety and emotional discomfort experienced by women, and better prepare them to manage abortion symptoms when at home and without provider care.

4.3 Materials and Methods

Women undergoing MA were recruited from October 2011 to May 2012 at two non-governmental organizations (NGOs) and two public sector primary care clinics in Cape Town, South Africa. Eligible women were scheduled to undergo MA at the clinic, over 18 years old, willing to comply with visit schedules, accessible by mobile phone and comfortable with receiving abortion-related messaging following enrolment in the study. Consent was in writing in the woman's language of choice. The study protocol was approved by the World Health Organization Research Ethics Review Committee, and the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee. The trial is registered with the Pan African Clinical Trials Registry (PACTR201302000427144).

The randomization schema was based on randomly permuted blocks of varying size with stratification by site. Participants were assigned (1:1) to the SOC control group, or the SOC + messaging intervention group. Sequentially numbered, opaque, sealed envelopes containing written indication of assignment were used. The outcome assessment included acceptability of the intervention thus interviewers were not blinded.

Both study groups received the standard abortion care from the clinic: abortion counselling and administration of 200mg mifepristone on-site; self-administration of 800mcg misoprostol (400mcg sublingual and 400mcg buccal for all study clinics) one to two days later at home; and a follow-up clinic visit two to three weeks later for assessment of abortion completion. At all clinics, standard counselling included information on home-use of misoprostol, abortion symptoms, possible medication side effects, signs of complications and the need for follow-up for assessment and initiation of a contraceptive method. When they received mifepristone, consenting participants were administered a baseline interview before randomisation. A second interview took place at the follow-up clinic visit; at this visit participants were remunerated ZAR 50 (about USD 5.80).

Women in the intervention group received a uniform program of automated text messages, starting on the day of their mifepristone. Thirteen timed text messages were sent including reminders to take medication as well as information on managing the bleeding, cramping and side effects (such as pain, vomiting and diarrhoea). Messages also highlighted potential

problems, such as excess or no bleeding, or fever in the days after the misoprostol (Table 4.1), and were available in three local languages (English, Afrikaans and isiXhosa). Women in the intervention group were given a phone number they could dial at no cost to themselves, if they wished to opt-out of the message program.

The baseline interview included items on socio-demographic information, social support, personal decision-making related to the abortion, and psychosocial measures of anxiety, depression and emotional discomfort. Study outcomes and acceptability of the intervention were determined at the second interview. Both interviews were conducted by trained fieldworkers using structured questionnaires. Participants were classified as lost-to-follow-up if they did not return for their clinic visit after a maximum of three phone contacts.

The primary outcomes were changes in anxiety, emotional discomfort and stress experienced between baseline and follow-up, as well as preparedness for the symptoms of the abortion. Anxiety and emotional discomfort were evaluated using the Hospital Anxiety and Depression Scale (HADS) (23) which has been used in other studies on induced abortion (24, 25) and Adler's 12-item emotional scale developed for abortion settings (26, 27). The HADS questionnaire contains 14 items, divided into 2 subscales of 7 items (each scoring 0-3) for measuring symptoms of anxiety and depression. Scores of >10 for each subscale are considered clinically significant (23). Adler's emotional scale includes two negative emotional factors or subscales, each consisting of a subset of correlated emotions. Socially-based negative emotions (SBNE) include guilt, shame and fear of disapproval. Internally-based negative emotions (IBNE) relate to the unwanted pregnancy and the abortion, and include regret, anxiety, depression, doubt and anger. Each item is scored from 1-5 according to strength of emotion. The mean value for each subscale is reported here as advised by Adler (personal email communication, 2013).

Table 4.1 Examples of the text messages, scheduling and type mapped to specific intentions

Message text	Day and time of delivery	Message content	Intention
Hi there, the pills u took at the clinic may make u bleed. If u do, it can be light, normal or heavy. But don't worry if u don't bleed. The pills you take at home tomorrow will make you bleed. Make sure u have pads and painkillers (Ibuprofen is good. Aspirin is bad so no Disprin or Grandpa).	Day 1 (day of mifepristone); 18h00	Information on symptoms and how to manage them	Reduce anxiety Improve preparedness
Hello! Just a reminder to take the pills you were given, 24 - 48 hours (1-2 days) after u took the pills at the clinic. Put a pill in each cheek and 2 under the tongue, and let them dissolve (break down) there. Take them without water! U can drink 30 min after.	Day 2; 09h00	Reminders on taking misoprostol correctly	Reassure on actions to be taken
When u take them, bleeding may start after 20 minutes (but later is OK too). If u vomit within 30 minutes of taking the pills, go back to the clinic for more.	Day 2; 09h04	Information on symptoms	Improve preparedness
Hey more info on the pills: if u get cramps, use heat or take pain killers. It can be pretty sore - don't be scared. U may feel sick, vomit, or get a runny tummy. It's not a problem.	Day 2; 18h00	Information on symptoms and how to manage them	Reduce anxiety Improve preparedness
Remember bleeding can be heavy! It's only a problem if u soak more than 6 maxi pads in 2 hours. Call or go to the clinic immediately if that happens.	Day 2; 18h04	Information on danger signs	Reduce anxiety Improve preparedness
Hi just a reminder that bleeding can be heavier than a normal period, and cramping can be worse. It's OK! Look after yourself :-) If you haven't started to bleed, don't worry. It's only a problem if bleeding didn't start within 2 days after you took the pills at home	Day 3; 18h00	Information on symptoms	Reduce anxiety Improve preparedness Social Support
Hi just a note that if you get a fever more than a day after you took the pills at home, and the fever lasts over 6 hours, please call or go to the clinic.	Day 5; 09h00	Information on danger signs	Reassure on actions to be taken
Remember that after the pills, bleeding usually lasts a week, but it can go on for as long as a month (that's unusual though!).	Day 7; 09h00	Information on symptoms	Reduce anxiety Improve preparedness
Hi hope you're good. You may still be spotting (a bit of bleeding or brown bits). If you're bleeding like a normal period or more, make sure you tell them this at your clinic appointment.	Day 13; 09h00	Information on symptoms, possible incomplete TOP	Reduce anxiety Reassure on actions to be taken

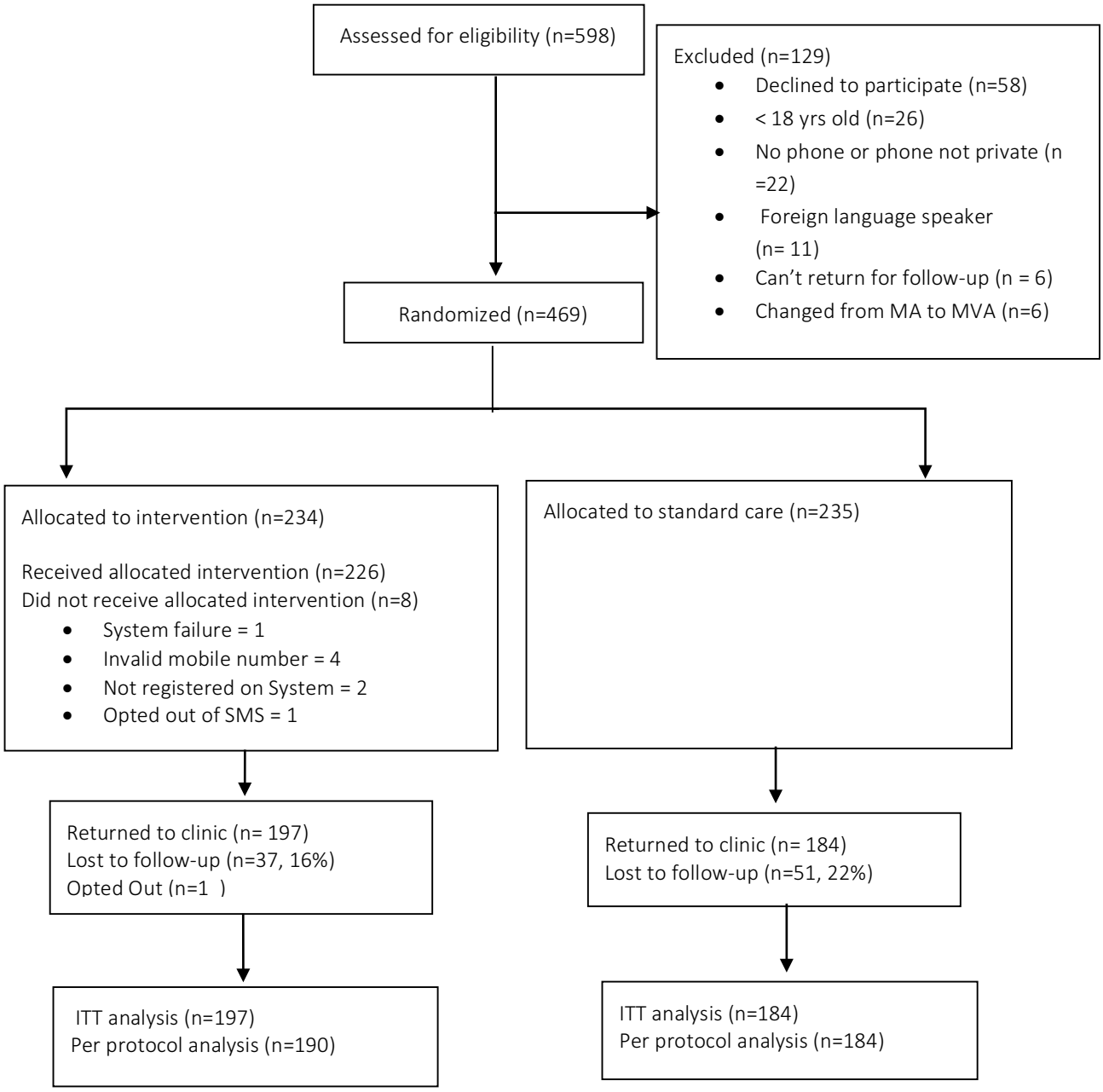
We also used the Impact of Event Scale-Revised (IES-R) which measures subjective stress related to a specific event (28, 29) and which has been used in previous studies measuring post-abortion emotional stress (24, 25). The IES-R contains 3 subscales of which we considered 2 appropriate for this study; the intrusion subscale (IES-I) measures frequency of intrusive thoughts related to an event and the avoidance subscale (IES-A) measures deliberate efforts not to think or talk about it (8 items per subscale, each scoring 0-4, maximum overall score for 16 items=64). Deriving cut-off scores from recommendations for the full 22-item scale (30) to the 16-item scale used here, summed overall scores greater than 24 for both IES-I and IES-A combined suggest clinically significant levels of stress. Preparedness outcomes included how well the information that was given or sent prepared women for the various abortion symptoms they experienced as well as their overall satisfaction with the abortion procedure. We used Likert-type scales of 4 levels ("No, not at all", "No, not really", "Yes, somewhat", "Yes, very much") to evaluate preparedness for pain, bleeding, side effects and abortion events as they occurred as well as overall satisfaction with the abortion. Secondary outcomes were the need for additional calls to the clinic prior to the scheduled follow-up visit and the duration and reason for additional calls.
Previous studies where no intervention was involved reported a decrease in mean anxiety of up to 50% from pre-abortion to 3 to 4 weeks post-abortion (27, 31). Using an estimate that anxiety in women receiving standard abortion care might decrease by 20% from initial clinic visit to follow-up assessment, a sample size of 230 in each study group at baseline would provide 85% power to detect a decrease in anxiety of 35% or more for the intervention group compared to 20% in the control group, with loss-to follow-up of 25%.
We analysed the primary outcomes by intention-to-treat followed by a per-protocol analysis in which 7 participants in the intervention group who did not receive the intervention were excluded. To detect whether results were dependent on whether the MA procedure was successful, the intention-to-treat analysis was repeated excluding women receiving manual vacuum aspiration (MVA) at follow-up due to a failed procedure, persistent bleeding or by request of the woman herself. A priori subgroup analyses were carried out according to pre-specified variables including study site, age, home language, education, prior abortion, and difficulty or not with the decision to have abortion.

In analysis, Cronbach's Alpha (α) was used to assess internal consistency of the psychosocial scales. Means and standard deviations were reported for continuous outcomes at baseline, follow-up and absolute differences from baseline to follow-up. Beta coefficients from linear regression models were used to estimate effect size for absolute differences. For IES-R scores which were measured only at follow-up, crude and adjusted analyses were performed where baseline covariates significantly differed between study groups. Differences in the effect of the intervention across the subgroups were assessed using an interaction term between treatment group and subgroup category in Analysis of Variance procedures. In analysing preparedness and satisfaction, we dichotomized scales into "Yes, very much" versus "Yes, somewhat", "No not really" and "No, not at all". Logistic regression, crude and adjusted for baseline differences, was used to estimate odds ratios with 95% confidence intervals for outcomes.

4.4 Results

Of the 598 women approached, fifty-eight declined to participate and 71 were excluded due to ineligibility (Fig. 4.1). Randomisation allocated 234 to the intervention and 235 to the control group. Table 4.2 shows the characteristics of participants. Study groups were similar at baseline for most characteristics with the exception of the HADS score for anxiety and the IBNE score, which were higher in the intervention group (p=0.007 and 0.017 respectively). Loss-to-follow-up was higher in SOC than in the SOC + messaging group at the second interview (p=0.102) (Fig. 4.1). For those returning to the clinic for follow-up, there were no significant differences between study groups for severity of pain (p=0.328) or bleeding experienced (p=0.193) during the abortion process.

Figure 4.1 Trial profile



Internal consistency of the measurement instruments (Cronbach's α) was 0.7 (baseline) and 0.8 (follow-up) for the HADS anxiety subscale and 0.8 (baseline) for the HADS depression subscale. For SBNE and IBNE, α was 0.7 and 0.8 (SBNE) and 0.7 and 0.8 (IBNE) at baseline and follow-up respectively. For IES-R subscales for intrusion and avoidance α was 0.8 and 0.9 respectively.

Table 4.2 Baseline characteristics of participants

Characteristic	SOC‡ n = 235		SOC+ Mobile ‡‡ n = 234		p-value*
Mean age in years (SD)	25.6 (5.4)		26.0 (5.6)		0.461
Home language (n(%))					0.446
isiXhosa	115	49%	104	44%	
Afrikaans	14	6%	22	9%	
English	80	34%	85	36%	
Other Language	26	11%	23	10%	
High school degree [n(%)]	187	80%	180	77%	0.484
Full time job/student [n(%)]	180	77%	184	79%	0.845
Formal housing [n(%)]	198	84%	196	84%	0.884
Mean gravidity prior to this pregnancy (SD)	1.1 (1.1)		1.2 (1.3)		0.207
Gestational age: 7-9wks [n(%)]	108	46%	104	44%	0.742
Had previous TOP [n(%)]	39	17%	34	15%	0.537
Married or in a stable relationship [n(%)]	188	80%	187	80%	0.982
Wanted to have this abortion [n(%)]	222	95%	224	96%	0.528
Difficult decision to have this TOP [n(%)]	130	55%	134	57%	0.671
Support at home during MA process [n(%)]	159	68%	157	67%	0.896
Mean score for socially based negative emotions (SD)	2.9 (1.2)		3.1 (1.2)		0.257
Mean score for internally based negative emotions: (SD)	2.6 (1.0)		2.9 (1.0)		0.021
Mean score for anxiety (SD)	10.2 (4.4)		11.3 (4.8)		0.007
Mean score for depression (SD)	8.4 (4.7)		9.1 (5.0)		0.149

‡ SOC = Control Group (Standard-of-care)

‡‡ SOC+Mobile = Intervention Group (Standard-of-care + messages)

* P-value associated with t-tests for comparison of means, Chi-squared tests for proportions

For the primary outcomes at follow-up, both study groups had lower mean scores for anxiety, SBNE and IBNE than at baseline. Intention to treat analysis showed anxiety decreased more in the SOC + messaging group than in the SOC group (β=1.3; 95% CI 0.3 to 2.4; p=0.013). Differences in SBNE and IBNE between baseline and follow-up were not significant for the two study groups (Table 4.3). The per-protocol analysis had similar results. Crude IES-R scores for avoidance and intrusion were similar for both groups at follow-up: Intervention versus control for avoidance (Mean=13.1, SD=7.3 vs Mean=14.4, SD=7.4, p=0.085) and for intrusion (Mean=9.0, SD=8.1 vs Mean=9.5, SD=8.3, p=0.541). When avoidance scores were adjusted for baseline anxiety, these were significantly lower for the intervention group (β=-1.8, 95% CI -3.2 to -0.4, p=0.015), but this was not so for adjusted intrusion scores (β=-1.4, 95% CI -2.9 to 0.2, p=0.083).

Table 4.3 Anxiety and negative emotions measured at baseline and follow-up clinic visits for the abortion

Outcome:	SOC group (n=184)			SOC+mobile group (n=197)			p-value
	Baseline Mean (SD)	Follow-up Mean (SD)	Absolute difference (BL-FU) Mean (SD)	Baseline Mean (SD)	Follow-up Mean (SD)	Absolute difference (BL-FU) Mean (SD)	
Anxiety	10.2 (4.3)	8.0 (5.1)	-2.3 (5.0)	11.4 (4.5)	7.8 (5.3)	-3.6 (5.3)	0.013
Socially based negative emotions	2.9 (1.2)	2.4 (1.2)	-0.6 (1.3)	3.1 (1.2)	2.4 (1.2)	-0.7 (1.32)	0.310
Internally based negative emotions	2.6 (1.0)	2.1 (1.1)	-0.5 (1.1)	2.9 (1.0)	2.1 (1.0)	-0.7 (1.0)	0.099

The analysis was repeated excluding those receiving MVA at follow-up (3%), representing cases for whom the abortion was unsuccessful. Results showed similar small, but significant decreases in anxiety for the intervention versus the control group between baseline and follow-up (β=1.5; 95% CI 0.5 to 2.6; p=0.004). Decreases in SBNE and IBNE were again similar for both study groups. The SOC + messaging group IES avoidance score was lower when adjusted for baseline anxiety (β=-1.7; 95% CI -3.1 to -0.2, p=0.025). The subgroup analysis showed no evidence for heterogeneity of the intervention across subpopulations except for education, with the intervention appearing more effective for those who had not completed high school than for those who had (p=0.047).

Outcomes measuring preparedness and acceptability of the abortion experience are shown in Table 4.4. Significantly more participants in the SOC + messaging group were very well prepared for the bleeding (OR=2.9; 95% CI 1.6 to 5.1), pain (OR=1.6; 95% CI 1.0 to 2.6), and other side effects (OR=1.8, 95% CI 1.1 to 2.9) experienced over the past 2 to 3 weeks related to the abortion, and were able to understand very well what was happening during the abortion (OR=2.7; 95% CI 1.2 to 6.0). There were no significant differences between the study groups regarding expectations or satisfaction. Repeating the analysis excluding the 12 cases who had MVA at follow-up did not alter results for preparedness, neither did adjusting for anxiety at baseline alter these results. Further comparison between study groups of being unprepared for the abortion symptoms showed that fewer women felt unprepared for bleeding in the intervention group (SOC + messaging=1% vs. SOC=7%, p=0.003), and none in the intervention group versus 5 (4%) in the control group felt unprepared for the events as they occurred during the abortion.

Table 4.4 Experience and acceptability of abortion

Outcome	SOC group (n=184)	SOC + mobile group (n=197)	p-value*
	N (%)‡	N (%)‡	
The information prepared the participant for: ‡			
Bleeding experienced	139 (75.5)	177 (89.9)	<0.001
Pain experienced	129 (70.1)	156 (79.2)	0.042
Side effects experienced	136 (73.9)	164 (83.3)	0.027

Events as they occurred during the abortion	163 (88.6)	188 (95.4)	0.016
Expectations coincided with actual experience of events	103 (56.0)	128 (65.0)	0.073
Satisfaction	108 (58.7)	131 (66.5)	0.116
Would recommend abortion method to a friend	120 (65.2)	143 (72.6)	0.121
Would have same procedure again	93 (50.5)	110 (55.8)	0.301

‡ Categories were “Very much” versus “somewhat”+ “not really”+ “not at all”.
* P-values for Chi-squared tests

Secondary outcomes showed no difference between study groups with 17 (9%) intervention and 18 (10%) control participants making calls to the clinic between their baseline and follow-up visit. The number of calls varied from 1 to 5 calls per participant calling in, and was similar for both groups (data not shown) as was the reason given to make the call. For both groups, the most common reason to call was to talk about bleeding symptoms, followed by pain symptoms and requests to reschedule the follow-up appointment.

The messages were highly acceptable to the SOC + messaging participants. 186/190 (98%) said that the messages helped them through their abortion, and 188/190 (99%) said they would recommend them to a friend. No adverse events were associated with the intervention, and only 1 participant stopped the messages early.

4.5 Discussion

These results suggest that a timed text message program can provide information preparing women for managing their abortion symptoms at home, and reduce abortion-related anxiety and stress during this time. The messages guided women through the MA process using a supportive tone without overtly addressing negative emotions; this may account for the effectiveness of the intervention for anxiety, as compared to SBNE and IBNE which typically arise in relation to the unwanted pregnancy and abortion decision.

As with other previous studies assessing emotional experience during or as a consequence of abortion (24, 27, 31-34), anxiety and strength of negative emotions in this study were greater prior to the abortion than afterwards. Anxiety levels in both our study groups were slightly above clinically significant levels (>10) at baseline, and dropped to subclinical levels

by follow-up. Similarly, post-abortion stress and anxiety, particularly in the short term, has been shown to be strongly mediated by pre-abortion levels (33, 34).

The small baseline differences between groups in this study for anxiety and IBNE scores were unlikely to result from failure of allocation concealment although we cannot exclude this possibility. Women were allocated to groups only after completion of the baseline emotional assessment and study fieldworkers were all well-known and experienced. Stratifying by site showed similar anxiety and IBNE differences between groups at baseline for all sites; this was significant only at one NGO (p=0.054). To adjust for the baseline differences between study groups we compared change in anxiety and emotions over the duration of the abortion process, rather than absolute values at follow-up. However, given the higher baseline anxiety in the intervention group, it is possible that this intervention benefits women who have high levels of pre-abortion anxiety, and this warrants further study.

Preparedness for managing the abortion symptoms at home was high in both groups, indicating good standard of care. The text message program significantly improved the proportion of those very well prepared, by strengthening and extending support for women beyond the clinic environment and providing guidance in 'real time'. The intervention did not have any significant impact on acceptability measures. It is worth noting however, that combining our results for "somewhat satisfied" with "very satisfied" resulted in 92% (controls) and 96% (intervention group) reporting overall satisfaction with their procedure which compares favourably with reports from other countries where home use of misoprostol is practiced (4-7).

Despite improving preparedness, the intervention did not reduce the numbers of participants calling the clinic between baseline and follow-up with questions relating to their abortion. We did not examine associations with the need to call due to limited sample size; however it is possible that women whose abortion symptoms deviated from the usual or expected course would need reassurance and that the intervention would not assist in these cases.

We had differential loss to follow-up with more non-returnees in the SOC group (Fig. 4.1). It is possible this could have introduced bias into our results, as women not returning might have felt more comfortable managing their abortion symptoms at home, compared to those who returned for clinic follow-up. However, we determined that there were no significant differences between study groups for all baseline characteristics among non-returnees.

This study adds to the growing body of evidence evaluating the use of mobile phones to strengthen and simplify medical abortion provision. This evidence comes at an opportune time as medical abortion services gradually expand into new areas in South Africa and other resource-limited settings, while at the same time there is increasing interest in the role of mobile phone interventions to strengthen health services. This mobile-based support was evaluated as an 'enhanced care' intervention, rather than as a substitute for in-clinic care. However, it could conceivably be offered to women as a helpful adjunct to telemedicine abortion services, or to those who have accessed abortion medication outside of the clinic environment such as through pharmacies. The messages had a very high level of acceptability, are inexpensive (less than USD $1 per woman), and can be set up so as to place no additional burden on healthcare workers. As such, this form of support has great potential especially where women have limited access to abortion-related support, or where levels of stigma are high. In addition to infrastructural requirements, mHealth interventions to strengthen healthcare require that text messages be adapted to meet the audience's needs and cultural nuances. Given locally acceptable content, we expect that our findings should be generalizable to other countries where mobile phone network systems are reliable and phone privacy is not a major issue.

The study has various limitations. Firstly, there was a bias towards a better-resourced population than the national average: study participants had a higher level of education and employment than the general population, two-thirds were recruited at NGO clinics where they had to pay for services (as opposed to public sector clinics where abortion services are free); and all study clinics were in an urban setting. The primary outcomes of anxiety and emotional discomfort are difficult to measure, however the internal consistency of the instruments used in the study was good, with Cronbach's α values similar to those reported elsewhere (27, 29, 30). The instruments measuring anxiety and emotional discomfort in the

study have been validated in abortion settings elsewhere; however these had not been validated previously for this particular study population.

In conclusion, text messages to women sent between their clinic visits for mifepristone and follow-up of early medical abortion can provide information and lead to reduced anxiety and stress and can alert them to possible complications. Given a no-cost opt-out phone number that recipients could text to stop the messages, they are highly acceptable to recipients and their privacy could be protected.

4.6 Acknowledgements

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Chapter 5

5.1 Paper 3. Self-assessment of medical abortion completion using a text questionnaire on mobile phones among South African women

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Paper overview

Paper 3 aimed to establish whether women could self-assess completion of their abortion using an automated interactive questionnaire on their mobile phones at 10 days post-misoprostol. The intervention group received standard abortion care and the mobile self-assessment, and also completed a paper version of the self-assessment at clinic follow-up 2-3 weeks later. The control group received standard abortion care only and completed the paper self-assessment at clinic follow-up. Completion of the mobile assessment was tracked by computer and all completed assessments were compared to providers' assessment at clinic follow-up.

Contribution to this thesis

This paper addresses question 3, part (a) of the thesis: How feasible and accurate is self-assessment of medical abortion completion using a mobile phone questionnaire on symptom history?

This was the first published study to use a fully automated mobile phone questionnaire on clinical history of abortion symptoms for women to self-assess their procedure. The study results showed that, given a brief training, the majority of women could complete a questionnaire on their phones and found this easy to do. However, both the mobile and paper assessments had low sensitivity and high specificity for predicting incomplete medical abortion. Thus, using an interactive questionnaire to self-assess completion of medical abortion on mobile phones is feasible in the South African setting, however the study confirmed that self-assessment using clinical history of abortion symptoms alone is not sufficiently accurate in identifying failed or incomplete abortions.

Role of the candidate

The candidate was co-responsible for conceptualization of the mobile questionnaire content. She was solely responsible for the study design and for the analysis performed. The candidate drafted and finalized the manuscript and was the lead and corresponding author on the paper.

5.2 Introduction

Medical abortion (MA) in the first trimester of pregnancy using mifepristone and misoprostol was approved by the South African Medicines Control Council in 2001 and has been provided in non-governmental organizations (NGO) and the private sector in South Africa since 2002. Only in 2010 did provincial guidelines authorize the use of the evidenced-based 200 mg dosage of mifepristone and approval was given to roll-out MA into public health facilities, led by the Western Cape Province and expanding into the rest of the country (1). Improving access to abortion services by introducing MA at more primary care facilities is expected to address some of the existing barriers to abortion care in South Africa, in particular the shortage of providers willing to perform surgical procedures (2-4).

Current MA standard care in both NGO and public sectors in South Africa involves mifepristone (200mg, oral) followed by misoprostol taken 1-2 days later at home (800mg; 400mcg sublingual, and 400mcg oral or buccal) and a follow-up visit at the abortion facility to assess abortion completion (1). Earlier studies using a regimen of 800mg mifepristone and 400mcg misoprostol at home reported a high level of acceptance among both women (3) and providers (4). In an effort to simplify MA provision and thus improve acceptability and access, the Planned Parenthood Federation of America in 2005 recommended that the in-clinic follow-up requirement be waived should it create undue hardship for women, if they could manage their follow-up with serum hCG testing at a facility closer to them (5). More recently the World Health Organization (WHO) 2012 guidelines specifically stated that routine in-clinic follow-up is not needed (6). These guidelines specify that to forego the follow-up visit, women must receive adequate counselling on potential complications and symptoms of ongoing pregnancy (6).

Barriers to the follow-up visit for women may include cost, need for privacy and the need to balance competing demands of home, family and work or school. In addition, studies have shown that as MA with mifepristone and misoprostol becomes better known and further de-medicalized, women increasingly don't return to the clinic if they consider the procedure to have been successful (7, 8). Tracing clients by telephone who have defaulted on their follow-up to reassure both providers and women that treatment has been successful can be

time consuming (9) and may not be feasible in resource-constrained settings like the South African public sector (personal communication, regional health manager 2010).

Research into follow-up strategies that avoid the use of ultrasound have included an in-clinic consultation between the provider and the woman either with or without a standard high sensitivity urine pregnancy test (10-12), or a set of questions on the abortion symptoms and a clinical consultation in combination with a low sensitivity urine pregnancy test (LSUPT) (8). Alternative out-of-clinic strategies involving providers included a standardized telephone questionnaire between provider and woman (13), or a telephone consultation with either a high sensitivity urine pregnancy test at 30 days (14) or a LSUPT at 14 days (15, 16). Web-based approaches have used an email consultation or an online form (17, 18). Studies exploring ways of safe self-assessment included a set of questions on the abortion symptoms experienced combined with a LSUPT (8), or with a semi-quantitative urine pregnancy test (SQUPT) (7, 19). A 2012 review of the evidence (20) pointed towards clinical history combined with a suitable LSUPT or SQUPT as the most promising method for women to accurately self-assess ongoing pregnancies or incomplete procedures.

Recent studies which used a standardized set of simple questions (9, 13, 15) most closely correspond to the design we implemented for our mobile-based self-assessment in this study. However, in 2011 at the start of our study it was not clear from the published literature exactly what wording the questions used and to what extent clinical judgement was included when the questions were asked by a provider. Also, many of these studies had been conducted in developed countries, although since 2013 limited evidence is emerging for low and middle income settings (7, 10).

The purpose of this study was to determine whether women could complete a self-assessment of their MA on their mobile phones while at home. We also aimed to determine the accuracy of the mobile assessment in predicting the clinician's assessment of need for manual vacuum aspiration or for additional misoprostol; we compare these results to those using the same self-assessment done on paper at the follow-up clinic visit.

5.3 Methods

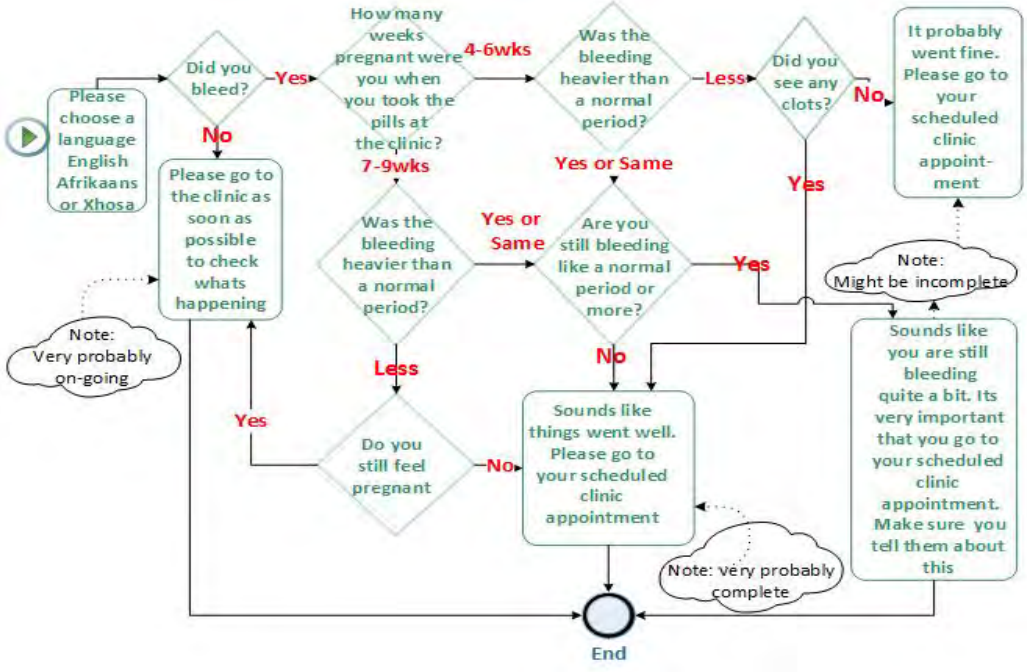
This study formed part of a larger randomized controlled trial investigating the benefits of sending information by text message on mobile phones to strengthen and simplify MA provision. The details of the text message program and the instruments used to measure their effectiveness in providing support to women for managing their abortion symptoms between clinic visits are reported elsewhere (21). Informed consent to join the study was in writing in the participant's language of choice. The study protocol was approved by the World Health Organization Research Ethics Review Committee, and the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee.

To design and develop the self-assessment component of the intervention the principal investigators reviewed the published literature, consulted with 3 key informants and interviewed all 6 providers at the study sites on which questions they used to determine success of the procedure. In addition, 20 consenting women were interviewed by a trained fieldworker at their in-clinic follow-up visit on any challenges they experienced in attending the follow-up clinic visit, their language preference for messages, as well as mobile phone ownership and usage.

Following piloting and iterative modification to improve the mobile intervention, the study was conducted from October 2011 to May 2012 at two NGO and two public sector abortion facilities. These included all clinics in the Cape Town metropole where a first trimester MA service was fully introduced as of May 2011, with the exception of one NGO facility where patient numbers were too low to be considered for the study. Eligibility was confined to women who were over the age of 18, who were eligible for an early MA (gestation up to 63 days by ultrasound assessment and no clinical contraindications), and willing to give informed consent. They also needed to have a working cell phone with them and to consider their phone private. Of the 598 women approached, 469 were enrolled, gave informed consent and were randomised on a 1:1 basis, to a standard-of-care (SOC) group (n=235) or a standard-of-care plus mobile (SOC+m) group (n=234).

The self-assessment questionnaire was implemented in two ways via mobile phone: through an instant message chat application that some participants already had installed on their phones; or through an unstructured supplementary service data (USSD) system which allowed users to interact with a server using text on their mobile phones. USSD costs 20 cents (South African) per 20 seconds of usage, so for our study purposes we sent women R10 ($1.10) airtime on their scheduled day for self-assessment and an automated text message prompting them to do it. Women needed to dial-in to access the questions and could select their language preference (English, Afrikaans or isiXhosa). The self-assessment was an automated interactive questionnaire routing the user through a maximum of 5 questions (Fig 5.1). There were 4 possible endpoints in the questionnaire that corresponded to on-going pregnancy, possibly incomplete, probably complete, very probably complete procedure. As the self-assessment design was experimental, when reaching an endpoint the user was not notified of these specific outcomes, but did receive an appropriate message (Fig 5.1) and a reminder to attend their clinic appointment as standard of care was maintained for all study participants (Fig 5.1). Details on the technical development of the full intervention have been published (22).

Figure 5.1 Self-Assessment routing diagram. Interpretation in Notes was not included in text to the User



At the clinic visit when women had received their mifepristone, trained fieldworkers administered a structured questionnaire recording socio-demographic information, reproductive history, and mobile phone usage. The pilot phase of the study had shown that women required a short training on how to access and complete the self-assessment. This training was done for those allocated to the SOC+m group on their phone or the fieldworkers' phone at this point and took a few minutes. Log files from the USSD system tracked women's access to and use of the self-assessment and which endpoint they reached. A second interview was conducted by fieldworkers with all participants attending their in-clinic follow-up visit for assessment of the abortion, prior to seeing the provider. All participants first completed a paper version of the mobile self-assessment without assistance from the fieldworker. Thereafter information was collected on participants' experience with doing the mobile self-assessment for those in the SOC+m group. Details of their clinical assessment were extracted from the woman's clinic file following her consultation with the provider.

5.4 Results

5.4.1 Provider interviews: Standard abortion care at study sites

All 6 providers interviewed were registered nurses, and most were experienced in providing MA (median 2.5 years; range 3 months – 5 years). In the public sector in-clinic follow-up was scheduled at 14 days after the clinic visit for mifepristone, and assessment involved a clinical history and ultrasound scan. At NGOs follow-up was at 21 days, and routinely included a high sensitivity urine pregnancy test as well as clinical history and ultrasound scan. According to providers, the scan image followed by the patients' account of their bleeding and cramping were key in the assessment of ongoing or incomplete procedures. Management at follow-up for ongoing pregnancy, persistent gestational sac and moderate to heavy persistent bleeding was manual vacuum aspiration (MVA). For cases where the scan showed retained products and there was some ongoing bleeding or significant amounts of spotting, women were either managed expectantly or given additional misoprostol and asked to return in a week.

5.4.2 Computer Logs: Use of the mobile self-assessment.

Eight women in the SOC+m study group did not receive the intervention due to mis-registration, invalid numbers or system failures. Of those receiving the intervention, 90% (204/226) tried to do the self-assessment and of those 204 who tried, 86% completed it (78% of 226) leaving 176 participants with completed mobile self-assessments as indicated by the USSD system log files. Many women completed the assessment a few times (27%, 47/176), sometimes with different results (7%, 12/176); we report the last result of completed assessments here. Of the 176, logs showed there were no cases for which the last completed assessment indicated "No bleeding" had occurred. In 4 cases the endpoint was "No bleeding" on the first try, but on subsequent tries this changed to either complete or incomplete/possibly incomplete. For 65% (115/176) of completed assessments the endpoints corresponded to complete successful abortion. The remaining 35% of assessments had endpoints suggesting incomplete abortions or ongoing pregnancies where it would be recommended to consult a clinician regarding additional care.

5.4.3 In-clinic follow-up: Provider assessment

In-clinic follow-up included 81% (381/469) of all enrolled participants. There were no significant differences in socio-demography, reproductive history, clinical assessment of abortion outcome or additional treatment between the two study groups for participants returning for follow-up (Table 5.1). Of all participants returning, 2% (7/381) did not wait to see the provider after completing the interview with the study fieldworker. Of the 6 women who had vacuum aspiration, 2 were assessed by a provider as probably having on-going pregnancies corresponding to an overall failure rate of 0.5%. Other indications included a persistent gestational sac, persistent bleeding or by request of the woman herself due to ongoing bleeding. Of all returnees, 25% (95/374) received additional misoprostol at follow-up with instruction to return to the clinic again the following week for evaluation.

Figure 5.2 Participant flow for assessment of medical abortion outcome

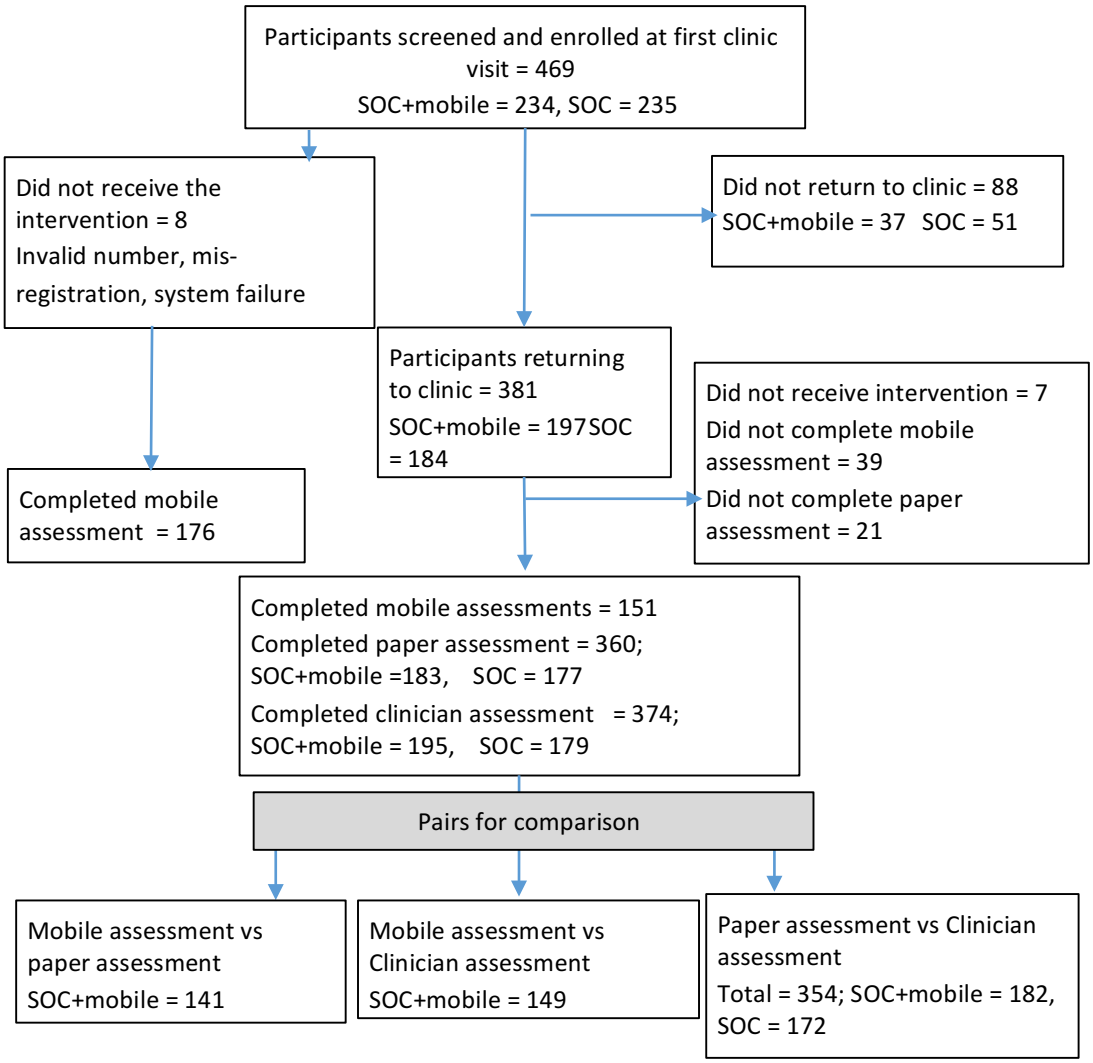


Table 5.1 Characteristics of participants returning to abortion clinic for follow-up

Characteristic	Standard of Care+mobile n = 197		Standard of Care n = 184	
Mean age, years (SD)	26.0 (5.6)		25.6 (5.4)	
Home language [n(%)]				
isiXhosa	92	47%	93	51%
Afrikaans	15	8%	13	7%
English	72	37%	60	33%
Other Language	18	9%	18	9%
Completed high school [n(%)]	151	77%	147	80%
Full time job/student [n(%)]	152	77%	139	76%
Formal housing [n(%)]	164	83%	157	85%
Gravidity prior to this pregnancy	1.3 (1.3)		1.1 (1.1)	
Gestational age: 7-9wks (vs 4-6wks) [n(%)]	91	46%	81	44%
Previous abortion [n(%)]	27	14%	31	17%
Clinician assessment:*	n = 195		n = 179	
No additional treatment at follow-up [n(%)]	136	70%	131	73%
Additional treatment at follow-up [n(%)]	59	30%	48	27%
Misoprostol only [n(%)]	53	27%	42	23%**
Vacuum aspiration [n(%)]	6	3%	6	3%**
Reason for vacuum aspiration:				
Ongoing pregnancy [n(%)]	1	0.5%	1	1%
Persistent/heavy bleeding [n(%)]	4	2%	5	2%
Persistent sac [n(%)]	1	0.5%	0	0%

* 7 missing – did not have clinician assessment
** Percentages do not add up to 27% due to rounding

5.4.4 Mobile self-assessment results

Results available for pairwise comparisons are shown in Figure 5.2. Of the participants completing mobile assessments and returning for in-clinic follow-up, 47/141 (33%) of women self-assessed on mobile to possibly have incomplete abortions or ongoing pregnancy with a recommendation that they return to the clinic for assessment. Accuracy of the mobile assessment to predict provider assessment of ongoing pregnancy or incomplete abortion requiring vacuum aspiration or extra misoprostol had a sensitivity of 46% and

specificity of 71% (Table 5.2). For the 6 women in the SOC+m group who received vacuum aspiration at follow-up, only 3 had completed the mobile assessment. Of these, only 1 identified her abortion on mobile as incomplete while the other 2 women had assessed their procedures to be complete.

For the 15 women interviewed at in-clinic follow-up but who did not try the self-assessment, reasons given were: difficulty with the first set of instructions, followed by not feeling like it and not having phone access at the time. Of those who tried, 93% (161/173; 2 had missing data) said it was easy or very easy to do. For those who said it was hard, problems were to do with mobile network or system failures. However, of the 24 who tried the assessment but truly didn't reach an endpoint (data from computer log), 50% (12/24) said that that they thought they had finished all the questions.

Table 5.2 Performance characteristics of mobile self-assessment in detecting incomplete abortion according to clinical assessment and treatment of incomplete abortion

	Clinical assessment (1)		Clinical assessment (2)	
	Incomplete abortion or ongoing pregnancy (MVA done or extra misoprostol given)	Complete abortion (No additional treatment required)	Incomplete abortion or ongoing pregnancy (MVA done)	Complete abortion (No MVA done)
Mobile self-assessment: Incomplete abortion or ongoing pregnancy	46% (22/48)	29% (29/101)	33% (1/3)	34% (50/146)
Mobile self-assessment: Complete abortion	54% (26/48)	71% (72/101)	67% (2/3)	66% (96/146)
	Sensitivity: 46%, Specificity: 71% Positive predictive value: 43% Negative predictive value: 74%		Sensitivity: 33%, Specificity: 66% Positive predictive value: 2% Negative predictive value: 98%	

5.4.5 Paper self-assessment results

Agreement between the paper self-assessment done at either 14 or 21 days and the mobile self-assessment done at 10 days after taking misoprostol was 69.5% (Kappa = 0.198) – indicative of only slight agreement. Agreement between the 2 assessments for a complete procedure was 71% and for an incomplete or ongoing procedure was 60%.

Accuracy of the paper assessment to predict provider assessment for need for vacuum aspiration or extra misoprostol is shown in Table 5.3. High specificity; 85%, for predicting need for MVA, and 91% for predicting need for MVA or extra misoprostol was at the expense of sensitivity. Forty-two percent for predicting need for MVA, 32% for predicting need for MVA or extra misoprostol.

We examined in detail the self-assessments, both mobile and paper, of the 2 cases that providers assessed to have on-going pregnancies. One was 24 years old, gestational age 4-6 weeks, had tertiary education and was from a francophone African country. She completed her mobile and paper self-assessment identically: She had bleeding less than a normal period, but thought she had passed clots or tissue, suggesting a complete abortion. The other (SOC group) was 23 years of age, gestational age 7-9 weeks, had completed high school, her home language was isiXhosa. Her paper assessment also showed bleeding less than a normal period, but she thought she didn't still feel pregnant.

Table 5.3 Performance characteristics of paper self-assessment in detecting incomplete abortion according to clinical assessment and treatment of incomplete abortion

	Clinical assessment (1)		**Clinical assessment (2)**	
	Incomplete abortion or ongoing pregnancy (MVA done or extra misoprostol given)	Complete abortion (no additional treatment required)	Incomplete abortion or ongoing pregnancy (MVA done)	Incomplete abortion or ongoing pregnancy (MVA done or extra misoprostol given)
Paper self-assessment: Incomplete abortion or	32% (34/106)	9% (22/248)	42% (5/12)	15% (51/342)

ongoing pregnancy				
Paper self-assessment: Complete abortion	68% (72/106)	91% (226/248)	58% (7/12)	85% (219/342)
	Sensitivity: 32%, Specificity: 91% Positive predictive value: 61% Negative predictive value: 76%		Sensitivity: 42%, Specificity: 85% Positive predictive value: 9% Negative predictive value: 99%	

5.5 Discussion

This study aimed to explore whether women undergoing MA could complete a self-assessment of their procedure on their mobile phones or on paper and whether these assessments would accurately predict the outcome of their MA, thereby providing an alternative to in-clinic follow-up. Our results showed that most, but not all, of our study population can complete an automated interactive questionnaire on their phones, however a short training is required to familiarize them with the process. While USSD was preferred over instant message chat, and therefore doing the assessment used some airtime, it is likely that technological progress will include other no-cost solutions in future. Future improvements on the design used here should include a feedback mechanism to the user that they have completed the questionnaire.

The unexpectedly low agreement between the mobile and paper self-assessment in this study may in part be due to timing. The questions and routing for both assessments were identical, however women completed the mobile assessment 10 days after taking their misoprostol and approximately 2/3 of the SOC+m group had their follow-up in-clinic visit 10 days after this (as per clinic protocol). More women (n=47) assessed their procedure as incomplete by mobile compared to their later assessment at follow-up on paper (n=20). Since the assessments included a question on persistent bleeding, it could be that the interval between the 2 assessments accounted for the differences. Other factors may include recall or errors in following the instructions on their mobile phones.

The study results showed that the self- assessment, either paper or mobile, was only moderately accurate in predicting ongoing pregnancies, or the need for a vacuum aspiration or extra misoprostol. This is similar to another recent study that reported modest success

for prediction of ongoing pregnancy or retained gestational sac using a standard set of questions (12). Accuracy of the self-assessment used in our study to predict a complete, successful abortion was good; however for out-of-clinic self-assessment the importance of timely identification of ongoing pregnancies before they progress into the second trimester is obvious. In the South African public sector, second trimester abortion services are only available in a small number of secondary and tertiary hospitals and the services are overbooked and difficult for women to access.

The high proportion of additional care rendered (25% of all participants received additional misoprostol) in our study may be indicative of "defensive" management by the providers. This figure is higher than usually reported elsewhere where additional treatment for ongoing pregnancy, persistent gestational sac or unacceptable persistent bleeding is usually 5 -10% (10, 23). For the public sector sites in the study, 1 provider was new to the service and may have needed more experience with assessing outcome, but this was not so for the other providers. In the interviews conducted in the formative part of this study, providers clearly described their management protocol with respect to assessment and decision for additional MVA at follow-up. However indications for additional misoprostol versus expectant treatment were less clear and it is possible that providers were inclined towards caution by issuing additional misoprostol more frequently than would be expected. Support and clarification for providers, possibly through discussion forums, may be helpful in understanding this issue more clearly.

We designed the mobile assessment to resemble a consultation as closely as possible, and used an interactive design with routing according to the user's answer to a question. This introduced some difficulties for the decision tree such as where to insert a question around pregnancy symptoms. Unpublished studies have shown that in many cases women in South Africa are not aware of pregnancy symptoms such as nausea or breast tenderness or do not make the association between pregnancy symptoms and being pregnant at early gestation (up to 63 days). In addition, our interpretation of the literature and our results suggest to us that a standardized self-assessment is a very different modality from a clinical consultation in which a trained provider exercises nuances of judgement at every point. A self-assessment needs to be simple, clear and conservative to avoid missing cases needing

treatment, but also should not cause unnecessary distress to users around the need for additional care.

A mobile assessment can be combined with support and informational text messages sent from a secure server – a package that can be offered to a woman at her first clinic visit. Messages on contraceptive method choice can be incorporated to form a comprehensive mobile package strengthening abortion care. If telemedicine for abortion is further incorporated into service provision, mobile-based self-assessment could be integrated into this approach. Outcomes can be tracked on-line by clinicians working at distance centres, and followed up with a telephone consultation, when needed.

Recent research suggests that a set of questions combined with an appropriate pregnancy test may be the best strategy for out-of-clinic self-assessment of abortion outcome (7, 16, 19, 20). In this study we did not ask women whether they preferred to do the assessment on their mobiles, on paper or with a provider; offering a choice of these options would be a good solution. Providing the questions on mobile may have a number of advantages over a paper version. People are less likely to lose their phones than a piece of paper and phone privacy is not an issue since users can initiate the assessment themselves when they feel it is private enough to do so. However, if a paper assessment is incorporated into a pregnancy kit, then its loss is much less likely, and women with unclear results could text a description of the assessment to the provider at the clinic to get clarification, or she could call.

5.6 Conclusion

Women undergoing MA in South Africa are for the most part able to complete a self-assessment on their mobile phone, given a short training session. A Self-assessment questionnaire may need to be combined with an appropriate pregnancy test to accurately predict the need for additional in-clinic treatment for ongoing pregnancies or incomplete abortions. Alternative follow-up strategies using mobile phones is in line with other developments that use technology to simplify and increase access to MA and hold promise for the future.

5.7 Acknowledgements

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Chapter 6

6.1 Paper 4. Self-assessment of medical abortion outcome in South Africa: A non-inferiority, randomized controlled trial.

Constant D, Harries J, Daskilewicz K, Myer L, Gemzell-Danielsson, K.

Publication Status: This manuscript has been prepared for submission to Obstetrics and Gynecology

Paper overview

This non-inferiority, randomized controlled trial compared two different modalities for guiding women on the use of a low-sensitivity urine pregnancy test: instruction-only was compared to a demonstration on the use and interpretation of the test. The primary outcome was accurate self-assessment of medical abortion outcome. The trial was conducted at six public sector primary care facilities in the Cape Town metropolitan district in the Western Cape, South Africa. In addition to the allocated intervention and receiving standard medical abortion care, all participants were given a low sensitivity pregnancy test and checklist for home self-assessment at 14 days, were sent automated text reminders, and asked to attend in-clinic follow-up 14-21 days later. Those not returning to the clinic were contacted by phone.

Thesis contribution and novelty

This paper addresses question 3, part (b) of the thesis: How feasible and accurate is self-assessment of medical abortion completion using a low-sensitivity pregnancy test (LSUPT) and symptom checklist in combination with text message reminders?

The study built on study 2 results, as reported in Papers 2 and 3. In Paper 4, instruction-only was compared to a demonstration of how to use the LSUPT. Feasibility and women's preferences for self-assessment were also reported and the issue of risk management in case of a false negative test result was discussed. The novel contribution of the study is the evaluation of different service delivery modalities for self-assessment supplemented by automated text messages, and inclusion of only public sector primary care facilities.

Role of the candidate

The candidate conceived of the study and the study design with support from Prof. K. Gemzell-Danielsson. The candidate obtained all ethical and site approvals, designed the data collection instruments, oversaw the study processes and performed the analysis. She also prepared the manuscript for submission and is the lead and corresponding author. An interim analysis was reported at North American Family Planning Forum, November 2015 and a poster with final results was presented at the European Society of Contraception and Reproductive Health 14th Congress, May 2016.

6.2 Introduction

Early medical abortion with mifepristone in combination with misoprostol was introduced into public sector primary care services in South Africa in 2010 (1). This local protocol required an in-clinic follow-up visit to identify a failed or incomplete procedure and to provide surgical or medical care if warranted. The percentage of women not returning to the clinic for follow-up has increased in recent years as the regimen is highly effective (2) and the additional visit can be burdensome, squandering limited resources of cost and time (3-7). Recognizing this, the World Health Organization (WHO) recommended that in-clinic assessment is not required if the abortion outcome could be confirmed (8). Self-assessment of medical abortion based on symptoms alone has been shown to be unreliable in South Africa and elsewhere (6, 9, 10). Suitable pregnancy tests, which can be supplemented by checklists have shown promising results in the US (11), Europe (5, 12) the UK (4, 11, 13, 14) and some low- and middle-income countries (3, 6, 15-17).

In South Africa, a single, simple, low-sensitivity urine pregnancy test (LSUPT) for home-use, together with a clearly worded checklist (CL), may be the most suitable approach to ensure prompt management of failed and incomplete procedures. It is unknown if this would be acceptable to women in the South African context and whether they could accurately interpret the LSUPT result without practice or assistance. However, having each woman conduct a practice test at the clinic would not be feasible due to provider time and costs of using two LSUPTs per woman.

The aim of this non-inferiority study was to determine whether instruction-only on the use of a LSUPT for self-assessment would be accurate within six percentage points compared to a demonstration using the LSUPT.

6.3 Materials and Methods

The study was conducted at six public sector primary level health care facilities, including one youth clinic for women under 25 years, in Cape Town, South Africa. To be eligible, women needed to be eligible for medical abortion using mifepristone with home-use of misoprostol, have a gestational age within 63 days, be 18 years of age or older, willing to

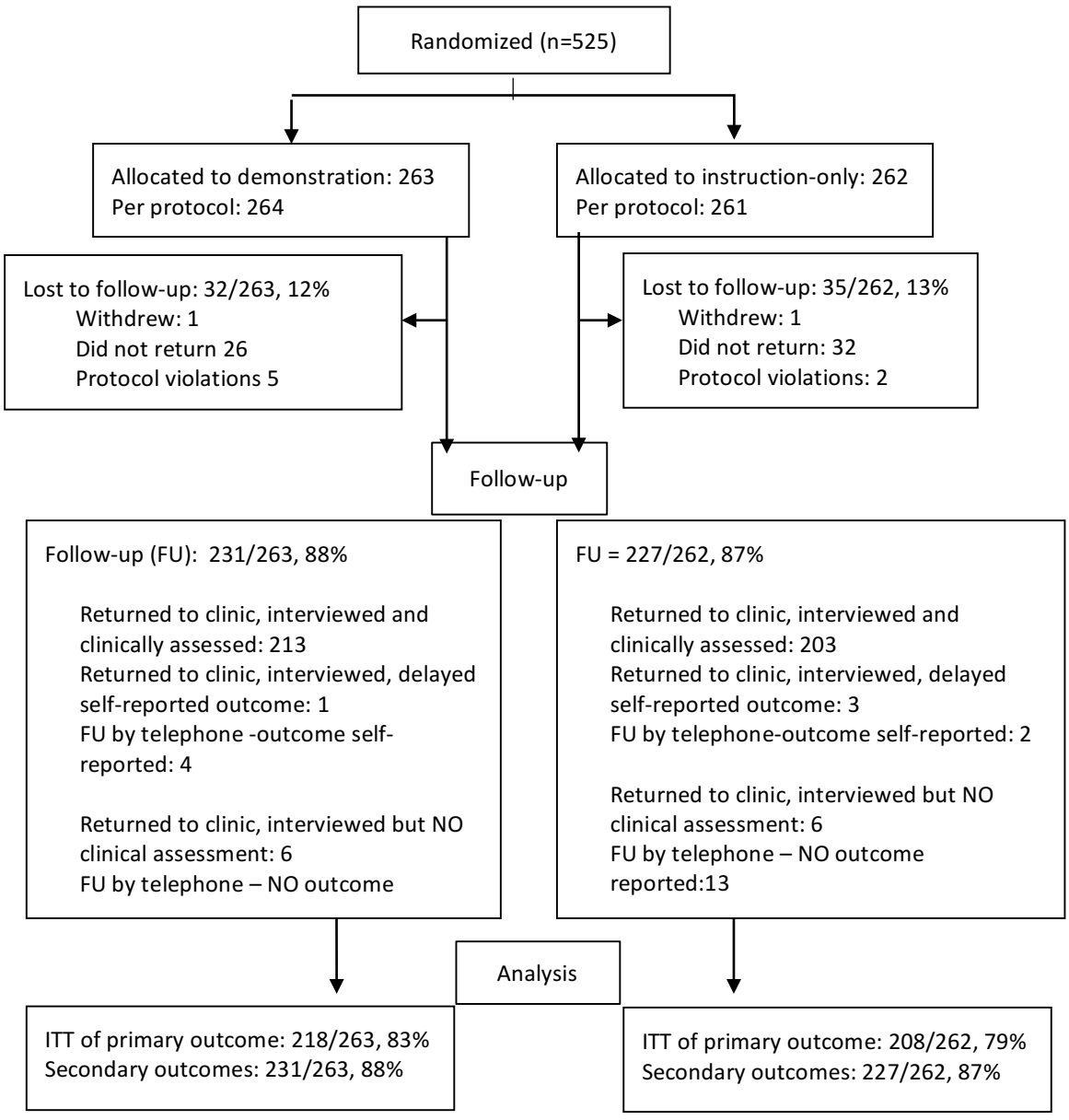
receive abortion-related text messages on their phone over the next 14 days, able to give informed consent and willing to attend a follow-up visit at the same abortion clinic. The study was approved by the University of Cape Town Human Research Ethics Committee.

A University of Cape Town investigator not involved with the study provided the computer-generated, fieldworker-specific randomization lists using Stata v. 13 with blocks of varying size 8-18. Allocation to study groups was in a 1:1 ratio and allocation slips were packed into sequentially numbered opaque sealed envelopes, corresponding to the randomization list, by an administrator uninvolved with the study. Fieldworkers opened the envelope corresponding to the participant enrolment number on conclusion of the baseline interview and conducted the intervention according to the assigned study group. Thus fieldworkers were blinded to the study group allocation only for the baseline interview; for all other study activities, fieldworkers, study investigators and participants were not blinded. Providers were unaware at all times to group assignment of participants.

Clinic staff conducted an ultrasound exam to determine gestational age eligibility for medical abortion for women requesting abortion of an unwanted pregnancy. Women within the gestational age limit were approached in the abortion facility waiting area by study fieldworkers to determine interest in the study. Eligibility screening was applied and informed consent administered to interested eligible women. Participants were enrolled and interviewed in a private area using a structured questionnaire, and on completion were allocated to a randomization group. Participants allocated to the demonstration group then conducted the checkToP® LSUPT (Veda Lab, France) on their own urine sample, guided by a fieldworker using pre-scripted instructions (Fig. 6.1). The checkToP® LSUPT detects urine hCG at concentrations of 1000 milli-international units/mL or more. The instruction-only group were given the same pre-scripted verbal instructions, but no demonstration. All participants were issued with a checkToP® test kit to be used on their first morning urine specimen at 14 days after mifepristone and a study CL. Participants then underwent standard medical abortion care with 200 mg of mifepristone, followed by 800 mcg of misoprostol, to be taken sublingually and buccally, at home 24-48 hours later, and at most clinics standard care was to offer a depot medroxyprogesterone acetate (DMPA) injectable or implant contraceptive immediately following mifepristone administration, in accordance

with WHO recommendations (8). Study participants' phone numbers were registered on the day of enrolment into a computer system which sent 19 timed, automated text messages over the next 14 days including reminders on storing the pregnancy test away from direct heat, taking their misoprostol, what to expect in terms of their abortion symptoms, pain management, excessive bleeding and other complications, conducting the pregnancy test and follow-up appointments. A similar messaging program has been described elsewhere (18, 19).

Figure 6.1 Flow chart of participants



Participants attending in-clinic follow-up were interviewed by a fieldworker prior to provider assessment. Interim clinic visits, the abortion experience, acceptability of text messages, pregnancy test result (participants were asked to draw this) and interpretation, and checklist responses were recorded. Women then saw the nurse provider for clinical assessment of their abortion outcome, which involved a clinical history and exam, in some cases a high sensitivity pregnancy test and an ultrasound exam if warranted. Providers were instructed by study investigators not to deviate from their standard care in evaluating abortion completion for study participants. On completion of clinical assessment, fieldworkers recorded participants' preference for follow-up methods and post-abortion contraceptive method, compensated them ZAR100 (~USD 7) for participation and extracted information on their abortion outcome from clinical records. Participants not attending clinic follow-up, were contacted the next day on their phone. Following three calls and two text messages, if no contact was made, they were considered potentially lost to follow-up, and one final contact attempt was made six months later. Participants completing the follow-up interview by phone received ZAR 50 compensation as airtime.

The primary outcome of the study was accurate self-assessment of abortion outcome (True Positives + True Negatives/Total); abortion outcome was defined in dichotomous terms: complete abortion versus failed or incomplete abortion with need for surgical intervention or additional misoprostol. A separate analysis for ongoing pregnancy compared to all other abortion outcomes was also performed. Sensitivity, specificity, negative and positive predictive values were also calculated for abortion outcomes. Secondary study outcomes included feasibility, acceptability and preference for self-assessment as well as post abortion contraceptive uptake.

To test our hypothesis that instruction-only was non-inferior to a demonstration of a LSUPT for accurate self-assessment of abortion outcome, we set the margin of non-inferiority to an absolute difference of six percentage points. Given a demonstration of the test, in combination with a checklist, we expected that 95% women would accurately assess their abortion outcome. The non-inferiority margin and this assumption were based on published studies (6, 20, 21), local providers' opinions, feasibility of implementing the test into service provision, as well as feasibility and cost of conducting the study. We calculated that a total

sample size of 416, with 208 in each group, would achieve 80% power to detect a non-inferiority margin difference between the demonstration and instruction-only group of 6% at significance level of 0.025. With a potential for loss to follow-up (LTF) of 20%, 520 participants were needed for enrolment at baseline.

Interview hardcopies were triple-checked for quality control and data were double entered into Epidata v. 3.1 by administrative assistants and errors in data entry corrected with reference to the hardcopies. Statistical analysis was performed using Stata v.13 (Tx). Study groups were compared at baseline using Chi-squared tests for categorical variables, t-tests for means of normally distributed continuous variables and Kruskal-Wallis tests for medians of non-normal continuous variables. All study outcomes were analyzed by intention-to-treat. Abortion outcomes were not evaluated from phone interviews where participants reported no clinic attendance, unless they self-reported abortion completion following a later phone call three to six months after their procedure. Non-inferiority of the instruction-only group for accurate assessment of complete abortion and of ongoing pregnancy was evaluated using the risk difference 95% confidence intervals (CIs). Sensitivity, specificity, negative and positive predictive values with 95% CIs were also calculated for abortion outcomes. Secondary outcomes were analyzed for all participants completing the follow-up interview in person or by phone; groups were compared using Chi-squared tests, with p-values of <0.05 considered statistically significant. Two sensitivity analyses were done by imputing missing values: firstly, with all missing values assigned as correctly self-assessing their abortion outcome and secondly with all missing values assigned as incorrect self-assessment. The trial was registered with ClinicalTrials.gov, number NCT02231619.

6.4 Results

Recruitment took place between 17 September 2014 and 09 June 2015. Five hundred and twenty-five women were enrolled into the trial, 263 into the demonstration group and 262 into the instruction-only group (Fig. 6.1). There were no differences between the groups at baseline (Table 6.1).

Table 6.1 Participant characteristics at enrolment by randomization group

Characteristic	LSUPT: Demonstration N=263	LSUPT: Instruction-only N=262	p
Age (years)			0.917
18-24	101 (38.4)	98 (37.4)	
25-29	72 (27.4)	76 (29.0)	
>=30	90 (34.2)	88 (33.6)	
Home language n (%)			0.671
isiXhosa	214 (81.4)	217 (82.8)	
Afrikaans	10 (3.8)	6 (2.3)	
English	25 (9.5)	28 (10.7)	
Other African language	14 (5.3)	11 (4.2)	
Travel Time (minutes)			0.744
0-15	53 (20.2)	60 (22.9)	
16-30	141 (53.6)	135 (51.5)	
>=31	69 (26.2)	67 (25.6)	
Education level n (%)			0.239
<Grade 12	116 (44.1)	129 (49.2)	
>=Grade 12	147 (55.9)	133 (50.2)	
Paid work n (%)	120 (46.1)	118 (45.2)	0.829
Formal housing n (%)	138 (52.5)	139 (53.1)	0.894
Prior pregnancies n (%)			0.394
0	52 (19.8)	42 (16.0)	
1	100 (38.0)	96 (36.6)	
2+	111 (42.2)	124 (47.3)	
Prior abortion n (%)	13 (4.9)	18 (6.9)	0.349
Prior medical abortion n (%)	6 (2.3)	8 (3.1)	0.578
Gestational age at enrolment			0.084
4-6 weeks	122 (46.4)	102 (38.9)	
7-9 weeks	141 (53.6)	160 (61.1)	
Did own HSUPT n/N (%)	217/259 (83.8)	222/257 (86.4)	0.408
Contraception in last year n (%)	173 (65.8)	163 (62.2)	0.395
Injectable n/N (%)	80/173 (46.2)	81/163 (49.7)	0.527
Oral n/N (%)	20/173 (11.6)	13/163 (8.0)	0.270
LARC (implant /IUD) n/N (%)	2/173 (1.2)	3/163 (1.8)	0.605
Condom (male or female) n/N (%)	78 (45.1)	70/163 (42.9)	0.693

There was 1 withdrawal per group, 7 protocol violations; 2 (demonstration) and 1 (instruction-only) were deemed not eligible for medical abortion following randomization, 3 (demonstration) and 1 (instruction-only) reported having an MVA within 1 week of mifepristone due to minimal or no bleeding following misoprostol, but no reason for MVA

was recorded in clinical charts. Clinic follow-up was scheduled at 14-21 days; some non-returnees' abortion outcomes were self-reported up to six months later in a phone interview. The primary outcome was confirmed for 218 in the demonstration and 208 in the instruction-only group. Some women completed their follow-up interviews at 14-21 days but did not have their abortion outcome clinically assessed at the time of the interview, and were included in the analysis of secondary outcomes. This larger sample consisted of 231 in the demonstration and 227 in the instruction-only group (Fig 6.1). For evaluation of the primary outcome, LTF was 4% higher in the instruction-only group. There were no significant differences in baseline characteristics between those LTF and those retained for the demonstration group. In the instruction-only group, younger women (median age = 25 vs. 28 years; p=0.277), and more living in better housing (68.5% vs. 49.0%; p=0.011) were LTF.

Additional clinic visits, abortion outcome and self-assessment results are shown in Table 6.2. There were no differences between study groups in the number of additional visit or calls made to the clinics nor in reasons for those visits and calls across study groups. Overall 3% of women contacted the clinic prior to the normal schedule, and none received additional abortion care at the unscheduled visit. The most common reason for the additional contact was related to bleeding, other reasons included, side effects, or the need for reassurance. There were no differences (p=0.858) in the proportion of incomplete abortions for retained products or persistent bleeding or ongoing pregnancies between demonstration and instruction-only groups (17/218, 7.8%; 17/208, 8.2% for incomplete abortions), (2/218, 0.9%; 1/208, 0.5% for ongoing pregnancies). There was one adverse event in the instruction-only group in which the participant sought hospital admission for symptoms of dizziness and weakness some hours after taking her misoprostol. She was stabilized in hospital, did not receive a blood transfusion, or any abortion-related treatment. She completed her self-assessment and follow-up clinic visit as scheduled.

There were no significant differences between study groups for abortion outcomes either by provider assessment, or by self-assessment using the LSUPT and CL, the LSUPT only or the CL only (Table 6.2). Of the 21/231 (9%) and 28/227 (12%) participants in the demonstration and the instruction group who reported a positive or unclear LSUPT result,

15 and 18 reported a faint second line positive for the LSUPT, and 6/231 (2.6%) and 10/227 (4.4%) reported clear double lines positive results (p=0.292).

Table 6.2 Additional visits, abortion outcome and self-assessment.

	LSUPT Demonstration	**LSUPT Instruction-only**	**p-value**
Made additional clinic visit or call	6/231 (2.6)	9/227 (4.0)	0.411
Primary reason for additional clinic visit or call			Fisher P=0.773
Bleeding	3/6 (50.0)	6/9 (66.7)	
Side effects	2/6 (33.3)	1/9 (11.1)	
Reassurance about abortion	1/6 (16.7)	2/9 (22.2)	
Abortion outcome	N=218/263 (82.9)	N=208/262 (79.4)	0.305
Complete abortion	199 (91.3)	190 (91.4)	0.858
Ongoing pregnancy	2 (0.9)	1 (0.5)	
Incomplete abortion	17 (7.8)	17 (8.2)	
Retained products	12/17 (70.6)	10/17 (58.8)	0.473
Excess bleeding	5/17 (29.4)	7/17 (41.2)	
Self-assessment outcome	N=231	N=227	
Checklist and pregnancy test: YES, return to the clinic	30 (13.0)	37 (10.1)	0.316
Checklist: YES, return to the clinic	24 (10.4)	23 (10.1)	0.928
Pregnancy test positive or unclear: YES, return to the clinic	21 (9.1)	28 (12.3)	0.261
Pregnancy test positive (excluding faint lines): YES, return to the clinic	6 (2.6)	10 (4.4)	0.292

Accurate self-assessment of abortion outcome was achieved by 191/218 (87.6%, 95% CI: 83.2-92.0) in the demonstration group and by 177/208 (85.1%, 95% CI: 80.3-89.9) in the instruction-only groups. There was no significant difference in relative risk between groups, however the 95% confidence interval of the risk difference of -2.5% (95%CI: -9.0 to 4.0 %) was beyond the non-inferiority margin by 3 percentage points and overlapped the null, (Table 6.3) indicating an inconclusive result for non-inferiority (Fig. 6.2). The two sensitivity

analyses did not alter this result (data not shown). Testing for heterogeneity showed no effect for age (p=0.185), prior use of a high sensitivity pregnancy test (p=0.175), home language (p=0.090), housing type (p=0.441), education (p=0.968) gestational (p=0.185) or prior abortion (p=0.232). Accurate self-assessment by LSUPT only for ongoing pregnancy, excluding test results reported as unclear or incorrectly done, also showed overlap of 95% CIs for the two groups. Similar to the primary outcome, the 95% confidence limit for the risk difference was outside the non-inferiority margin and crossed the null (-2.9%; 95% CI: -8.7 to 2.9%), signifying that non-inferiority for instruction-only was inconclusive.

Sensitivity and specificity, negative and positive predictive values for self-assessment of abortion outcome for the two study groups had overlapping 95% CIs (Table 6.3), as for ongoing pregnancies. Of the 3 ongoing pregnancies, there was 1 false negative test and 1 true positive test for ongoing pregnancy in the demonstration group and 1 true positive test in the instruction-only group. Comparing self-assessment of abortion outcome of the combined LSUPT and CL to the LSUPT alone showed that the combined LSUPT and CL was less accurate than using the LSUPT alone (Table 6.4; McNemar test for repeated outcomes, p <0.001).

Table 6.3 Comparison between study groups

1) Self-assessment with LSUPT and Checklist of incomplete abortion and 2) Self-assessment with LSUPT of ongoing pregnancy.

	1) Incomplete abortion: Provider: vs. Self-assessment: LSUPT+ Checklist			**2) Ongoing pregnancy Provider vs. Self-assessment: LSUPT only***		
Test statistic	Demonstration	Instruction-only	Risk Difference	Demonstration	Instruction-only	Risk Difference
	nSA/PT+CL / NCL	nSA/PT+CL / NCL		nSA/PT* / NCL	nSA* /PT / NCL	
Accuracy (95%CI)	191/218 87.6% (83.2-92.0)	177/208 85.1% (80.3-89.9) p=0.449	-2.5% (-9.0 to 4.0)	197/216 91.2% (87.4-95.0)	181/205 88.3% (83.9-92.7) p=0.324	-2.9% (-8.7 to 2.9)
Sensitivity (95% CI)	11/19 57.9% (33.5-79.7)	12/18 66.6% (41.0-86.8)	-	1/2 50% (1.3-98.7)	1/1 100% (2.5-100)	-
Specificity (95% CI)	180/199 90.5% (85.5-94.2)	165/190 86.8% (81.2-91.3)	-	196/216 91.6% (87.0-94.9)	180/204 88.2% (83.0-92.3)	-
Predictive Value (+) (95% CI)	11/30 36.7% (19.9-56.1)	12/37 32.4% (18.0-49.8)	-	1/19 5.3% (0.1-26.0)	1/25 4% (0.1-20.4)	-
Predictive Value (-) (95% CI)	180/188 95.7% (91.8-98.1)	165/171 96.5% (92.5-98.7)	-	196/197 99.5% (97.2-100)	180/180 100% (98.0-100)	-

* Unclear LSUPT results excluded for this outcome

Table 6.4 Comparison of accuracy of self-assessment of abortion outcome using LSUPT alone to LSUPT with CL.

	Accurate self-assessment of abortion outcome n/N, % (95%CI)		
	Demonstration	Instruction-only	P-value for pooled groups (McNemar test for repeated values)
Intervention			
LSUPT only	198/218 90.8% (86.2-94.3)	180/208 86.5% (81.1-90.9)	p<0.001
LSUPT+CL (95%CI)	191/218 87.6.% (82.5%-91.7%)	177/208 85.1% (79.7%-89.6%)	

There were no significant differences between study groups for feasibility, acceptability and follow-up preferences (Table 6.5). Almost all (99.6%, 456/458) in both study groups did their pregnancy tests. Most (99.0%, 405/409) did them at 10 days or later after their mifepristone, 99.1% (454/458) found the test easy or very easy to do, and 98.5% (451/458) preferred self-assessment to an in-clinic appointment to check if their abortion had been successful. Most were satisfied with their abortion (97.8%, 447/457), would recommend the method to a friend (82.0%, 373/455) and would want the same method, should they need another abortion (86.2%, 392/455). Ninety-six percent (438/458) in both groups started a contraceptive method; just over half in both groups initiated the method at their mifepristone clinic visit, known as “quick start” of contraception. Most commonly the quick-start methods were injectable short-term methods, followed by the contraceptive implant, with some participants receiving pills (data not shown).

Figure 6.2 Study group differences for accurate self-assessment

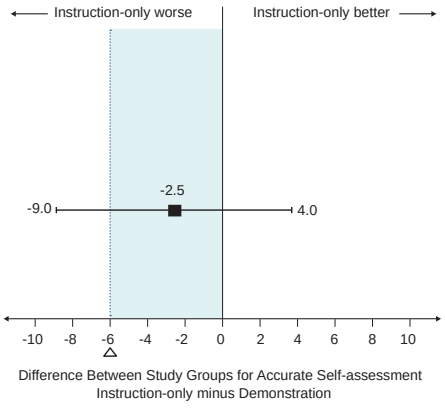


Table 6.5 Feasibility and acceptability of self-assessment and abortion experience

	Demonstration	Instruction-only	P-value
Did pregnancy test at home	230/231 99.6%	226/227 99.6%	0.990
Did pregnancy test at >=10 days	206/208 99.0%	199/201 99.0%	
Easy or very easy to do pregnancy test	230/231 99.6%	224/227 98.7%	0.307
Preferred follow-up method			
Return for in-clinic assessment	3/231 1.3%	4/227 1.8%	
Pregnancy test, with or without CL & SMS, contact clinic if need to	228/231 98.7%	223/227 98.2%	
Satisfied or very satisfied with abortion	225/231 (97.4%)	222/226 (98.2%)	0.545
Would recommend abortion method to a friend	193/229 (84.3%)	180/226 (79.7%)	0.199
Would have same procedure, if needed abortion again	197/230 (85.7%)	195/225 (86.7%)	0.754
Started post-abortion contraception	221/231 (95.7%)	217/227 (95.6%)	0.580
Contraception started at mifepristone visit	118/221 (53.4%)	115/217 (53.0%)	0.580

6.5 Discussion

The study showed that accuracy of self-assessment of medical abortion given instruction-only could be inferior to a demonstration on how to use the test, although this was not conclusive. Taking into account the single false negative result for the LSUPT in the demonstration group, the high percentage of provider intervention (7.9 %), and the preponderance of faint line positive tests observed among those with complete abortions, the overall self-assessment accuracy was generally good. Combining both our study groups together, 88.7% (95% CI: 85 1-91.7%) were able to self-assess with certainty that their procedure was complete with no need for additional treatment (specificity), representing the proportion of women who could safely forgo in-clinic follow-up. In total, 89.5% (95% CI: 86.2 – 92.3) in our study could accurately self-assess no-ongoing pregnancy (specificity). This is less than reported in studies using the MLUPT (6, 15), but similar to other studies using

the LSUPT (4, 11). Taken together with high acceptability and preference expressed by our study participants, self-assessment with a LSUPT can be recommended for service provision in the South African context.

Research from other settings using a LSUPT has also reported occasional false negative results for ongoing pregnancies (3-5). In all of these cases of ongoing pregnancy, as in our study, women received their abortion. Although more frequent than for the MLUPT, false negative LSUPT results are rare overall, and if conservative criteria are used for self-assessment of ongoing pregnancy as done elsewhere (4), it is highly unlikely these cases would not receive their abortion. However, as immediate rather than delayed start of implant and injectable contraceptives is encouraged by providers in South Africa, an ongoing pregnancy could be confused for amenorrhea from hormonal contraception. In these cases, recognition of ongoing pregnancy and a second abortion procedure would be further delayed.

In our study, as in other studies, adding the CL detracted from accuracy of self-assessment using the LSUPT or MLUPT alone, and the value of the CL has been questioned (6). A similar study in LMIC settings suggested women might simply be instructed to return if they experience bothersome symptoms or have a positive test (15). Currently, in the UK where self-assessment using the LSUPT is offered, women sign an opt-out agreement if they prefer not to be contacted by the clinic for follow-up. This document also explains signs of incomplete procedures or complications and replaces a checklist (4). The LSUPT used in our study included these instructions in the packaged test-kit and future implementation in South Africa should involve additional counselling to ensure these are clearly understood by women. Women preferring self-assessment can be counselled, if necessary in groups, and be given a simulated demonstration on the use of the LSUPT. Women's confidence in self-managing their medical abortion may increase over time as this approach becomes better known generally. Providers trust and support for women's choice of self-assessment is also likely to grow as this become more commonplace

A limitation of the study was that the randomization only impacted on conducting and interpreting the pregnancy test, and the study outcome included assessment of incomplete

abortion, where the pregnancy was ended but additional treatment was indicated for bleeding or retained products. In addition, we did not set out to validate the pregnancy test, nor was the study powered to detect ongoing pregnancy. Nonetheless, the complete abortion rate was the same between study groups, as were the self-assessment outcomes from the checklist, and we believe that the study results may be accepted as accurate.

There was differential LTF between study groups, with participants missing not at random which could have biased our findings. However, the sensitivity analyses performed suggest a robustness in the study results. In addition, in determining sample size, we estimated that 95% of women in the demonstration arm would accurately self-assess their abortion outcome. In the study, this was 88% overall, and thus the study was slightly underpowered for the non-inferiority margin set. A larger sample might have resulted in a smaller 95%CI for the risk difference between study groups. Our study population is representative of the urban population attending free public sector health facilities in South Africa, classified as a high-middle income country. Fifty-three percent of participants had completed their school high education, all had use of a mobile phone, and all were able to read their home-language, thus our study results are likely to be generalizable to similar settings elsewhere in South Africa and globally.

6.6 Conclusion

In this study, providing brief verbal instructions compared to a guided demonstration on the use of a low-sensitivity urine pregnancy test did not impact conclusively on accurate self-assessment of abortion outcome. Combined with appropriate supporting material, the low-sensitivity urine pregnancy test is feasible and acceptable for use in public sector abortion clinics in South Africa. The inclusion of automated text reminders is well-liked by women and when combined with the low-sensitivity urine pregnancy test, is much preferred to clinic follow-up.

6.7 Acknowledgements

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Chapter 7

7.1 Paper 5. Clinical outcomes and women's experiences before and after the introduction of mifepristone into second-trimester medical abortion services in South Africa.

Constant D, Harries J, Malaba T, Myer L, Patel M, Petro G, Grossman, D.

Publication Status: In Press: PLoS One (25/08/2016)

Paper overview

This paper documented clinical outcomes and women's experiences following the introduction of mifepristone into public sector second-trimester medical abortion services, in comparison to historic cohorts receiving misoprostol-only. The study used a pragmatic study design, comprising repeated cross-sectional observational studies documenting these outcomes in the Western Cape public sector second trimester medical abortion service. Data were collected in 2008 and in 2010when misoprostol was standard care, and again in 2014 following the introduction of mifepristone. The same study instruments were used for each round of data collection. Women were interviewed during hospitalization and clinical details were extracted from medical charts following discharge.

Contribution to this thesis

This paper addresses question 4 of the thesis: what are the improvements in second trimester medical abortion care following the introduction of a mifepristone-misoprostol regimen into the South African public sector service?

This study demonstrated an improved model of service delivery that could serve the country as a whole, as well as other LMICs where mifepristone has been approved, but not incorporated into second trimester services. Off-site self-administration of mifepristone and early morning admission for misoprostol were resource-saving strategies. Lessons to be learnt included avoiding high rates of curettage as documented during this early phase of the new regimen.

Role of the candidate

The candidate was responsible for coordinating the 2010 and 2014 projects, and for data management overall. She was also responsible for developing analysis-ready data for all datasets and performed the analysis for this study. The candidate drafted and finalized the manuscript and was the lead and corresponding author on the paper.

7.2 Introduction

Accessible and effective provision of second-trimester abortion is particularly important in settings where a high proportion of women seek abortion in the second trimester, as is common in low- and middle-income countries (LMICs) (1, 2). South Africa's abortion legislation of 1996 allows for abortion between 12 and 20 weeks for several indications, including on socio-economic grounds (3). In the Western Cape Province of South Africa, 28% of all abortions are performed in the second trimester, which is higher than reported for the United States, United Kingdom, Nepal and the Russian Federation (4-8), although lower than in some parts of India (9, 10).

Both surgical and medical methods for second-trimester abortion are considered safe and effective when performed by skilled providers, and major complications are rare events (11-13). However, shortages of physicians trained in dilation and evacuation (D&E) are a common problem, and medical methods using recommended regimens are increasingly used in resource-constrained settings (1, 2, 14, 15). Randomized controlled trials (RCTs) comparing the combined mifepristone-misoprostol regimen to misoprostol used alone in the second trimester have consistently shown improvements in efficacy and time to abortion (14, 16-18). Observational studies have documented similar outcomes following introduction of the combined regimen into services (19-24). However, even in LMICs where mifepristone combined with misoprostol is standard of care for first-trimester abortion, this regimen has been less commonly used for later procedures. Possible reasons include limited recognition of its greater efficacy over the misoprostol-only regimen for second trimester procedures, and that comparatively less effort has been directed to advocating for the use of mifepristone than for first trimester procedures, as the procedure take places in hospital settings (14). In addition, in South Africa, mifepristone is not registered for use in the second trimester, and it was only added to the national essential drug list for this indication in 2012.

Medical methods for abortion have been shown to be acceptable to women in many settings, both for first- and second-trimester procedures, as well as for managing incomplete abortion (11, 17, 25-28). Factors reducing acceptability of first-trimester medical abortion with mifepristone include treatment failure, extreme pain and bleeding,

inconvenience and anxiety (26-29). In contrast, for second-trimester medical abortion, prolonged induction duration and high levels of pain reduce women's acceptability and satisfaction with their procedure (17, 30).

With a shortage of physicians in the South African public sector who are skilled in D&E and willing to provide the service (31), medical abortion is generally the standard of care in the second trimester. In South Africa prior to 2013, second-trimester medical abortion was provided using a regimen of misoprostol only.

Previous research among women undergoing second-trimester abortion in South Africa using the misoprostol-only regimen reported safe abortion provision; however, the study reported delays in accessing care, and prolonged hospitalization beyond 2 days in many cases (11). The mifepristone-misoprostol regimen for medical abortion was introduced into several public sector hospitals in the Western Cape Province in 2013 and 2014.

Implementation of new second-trimester abortion services into public sector teaching hospitals in LMICS s can be challenging as limited capacity, high patient-to-staff ratios, extensive referral areas, complicated referral pathways, high rates of staff rotation are commonplace (1, 7, 11, 32-34). We aimed to add to the limited literature on second-trimester abortion from such settings by describing clinical outcomes and women's experiences following the introduction of mifepristone into medical abortion services and comparing these to previous cohorts receiving misoprostol only.

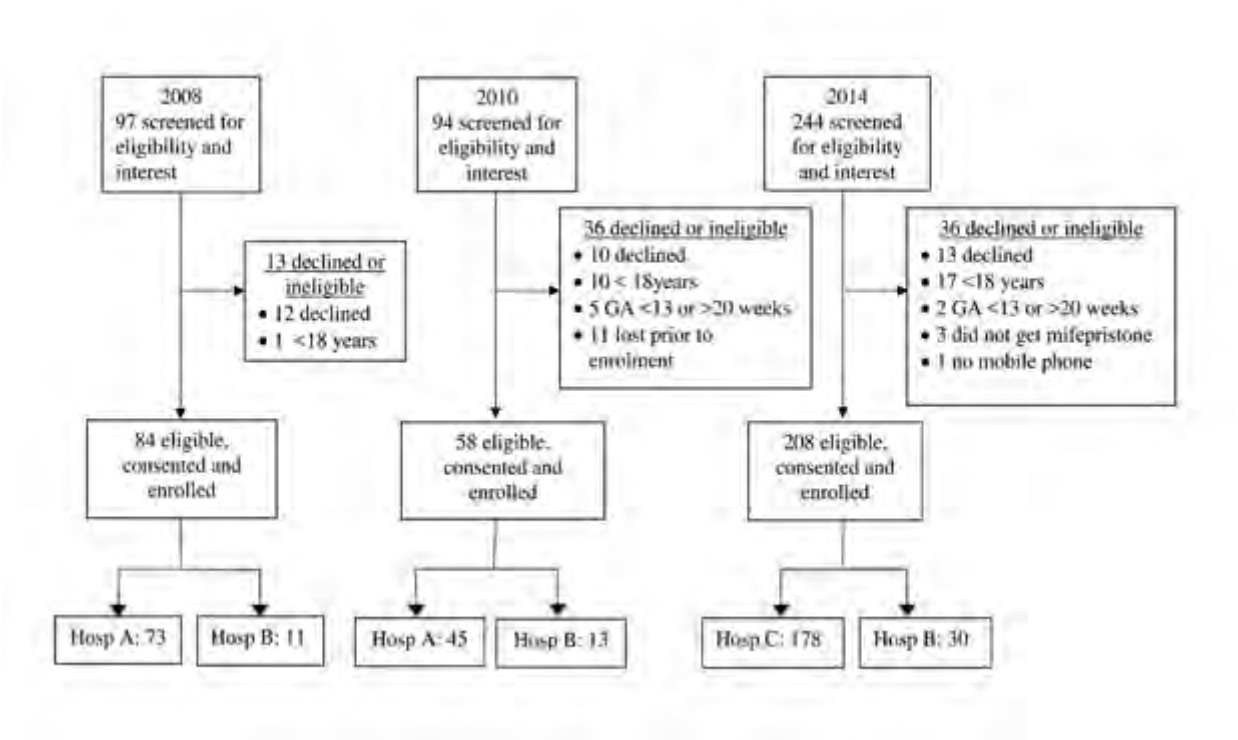
7.3 Methods

7.3.1 Study design and participants

The historic cohorts receiving misoprostol-only were recruited from February through July 2008 and April through August 2010 at Obstetric and Gynecology departments of two public sector teaching hospitals (Hospitals A & B, Fig. 7.1) in the Western Cape providing medical abortion. Both hospitals are general specialist hospitals with 24-hour availability of surgical, anesthesia and blood transfusion services. Hospital A is in an urban and Hospital B in a semi-rural location, both with extensive referral areas. These two cohorts (2008 and 2010) were

combined into a single misoprostol-only group for this analysis. The third cohort (referred to as the mifepristone group) received mifepristone for self-administration at home followed by admission for misoprostol and was recruited from October 2013 through June 2014, also at two public sector hospitals. This combined mifepristone-misoprostol regimen was introduced into a newly expanded service at Hospital C, an urban, highly specialized facility, and into Hospital B from the previous 2008/2010 cohorts, with Hospital A switching from medical abortion to a D&E service (Fig 7.1). In South Africa, second-trimester medical abortion takes place in secondary level hospitals. Hospitals A, B and C were the only facilities in the Western Cape providing the service. Additional hospitals in the province provide limited D&E services (11). Ethical approval for all studies was given by the University of Cape Town Human Research Ethics Committee and the Allendale Investigational Review Board.

Figure 7.1 Participant recruitment to 2008, 2010 and 2014 cohorts



7.3.2 Procedures

In all cohorts, women requesting abortion were referred from primary care facilities with a confirmed pregnancy and gestational age dating by ultrasound. At study facilities, women

underwent further examination by physicians, received counselling and provided consent for the procedure, and a booking was arranged for admission to the general gynecology ward.

Study recruitment and procedures were similar for all cohorts. During the recruitment periods, within logistical constraints of one fieldworker per facility, all women undergoing medical abortion were approached for participation. Eligibility criteria included having been assessed by physicians and deemed medically appropriate for the service, having consented for medical abortion, being age 18 years or older, pregnant with a gestational age at time of mifepristone administration between 12 weeks 1 day and 20 weeks 0 days, and able to communicate in English or isiXhosa. Written informed consent to participate in the study was obtained following a confirmed booking for admission or on admission. Trained, experienced study fieldworkers not involved in service provision administered structured face-to-face interviews recording socio-demographic information, reproductive history, and women's experience of the abortion procedure. Questions were standardized and identical for all cohorts. Interviews were conducted initially after admission and again prior to discharge or within 48 hours thereafter by phone. Investigators abstracted clinical information related to the abortion from hospital records after discharge. Fieldworkers conducted an additional follow-up telephone interview 2-4 weeks after discharge to collect information about delayed complications for the mifepristone group.

7.3.3 Study outcomes

The primary outcome was 24-hour fetal expulsion rate (defined from first misoprostol dose to fetal expulsion; time of fetal expulsion was not recorded for the 2008 cohort). Other clinical outcomes included drug administration, time-to-fetal expulsion, rates of uterine evacuation for placental tissue and time-to-abortion completion (defined as time from first misoprostol dose to placental expulsion if no evacuation, or completion of evacuation, if done). In addition, hospitalization duration, analgesia, major complications (death, abdominal surgery, hospital readmission, hemorrhage requiring transfusion, infection treated with intravenous antibiotics and/or seizure) and post-abortion contraception were recorded. Women's experiences included presence of side effects (yes/no), and level of

pain, overall satisfaction (how would you describe your overall satisfaction with your abortion?) and acceptability (would you recommend the method to a friend?) measured on 5-point scales.

7.3.4 Analysis

Data were analyzed using Stata v. 13. Data for the 2008 and 2010 misoprostol-only cohorts were combined to improve statistical power of the historical data. Missing data were not imputed, and only valid percentages were reported. Descriptive statistics were reported for participant characteristics and study outcomes. Five point scales were collapsed to three categories for analysis, and groups were compared using Chi-squared tests for proportions or Kruskal-Wallis tests for medians. Kaplan-Meier analyses and log-rank tests were used to compare unadjusted time-to-fetal expulsion between mifepristone and misoprostol-only groups. To adjust for confounding and differences in drug administration, hazard ratios (HRs) for time-to-expulsion were calculated for exposure to mifepristone, adjusted for significant covariate differences identified a priori, (age, gestational age, prior vaginal delivery, parity, prior abortion) and stratified by quartiles of total misoprostol dosage. HRs were also calculated for the majority subgroup of participants receiving their first misoprostol dose via the vaginal route of administration (PV).

7.3.5 Sample size

The desired sample size was based on fetal expulsion rate, as the more direct measure of abortion effectiveness compared to abortion completion, which is dependent on physician practice with regard to curettage. Reported fetal expulsion rates within 24 hours range between 93 – 97% for the mifepristone-misoprostol regimen (13, 15) and for our misoprostol-only 2010 cohort was 72% (95% CI: 63% – 81%). To be conservative, we based our sample size calculation on a 90% fetal expulsion rate within 24 hours for the mifepristone-misoprostol group and 81% for the misoprostol-only group (the upper limit of the 2010 cohort 95% CI). We calculated that a sample size of 131 participants in the mifepristone cohort would suffice to detect a significant difference in fetal expulsion rate within 24 hours between the mifepristone and the misoprostol-only cohorts using a one-

sided 2.5% level test of significance, with a power of 90%. To allow for analysis of covariate effects, we planned to include 200 women in the mifepristone cohort.

7.4 Results

For the 2008 and 2010 misoprostol-only and mifepristone cohorts respectively, 86% (84/97), 62% (58/94) and 85% (208/244) of women screened for participation were enrolled into the study. Overall, enrolled women constituted 50% (350/700) of all women undergoing medical abortion at study facilities during the study periods. Participant enrolment for all cohorts, including reasons for non-participation are shown in Fig 7.1.

7.4.1 Participant characteristics

Significant differences in participant characteristics between the 2008 and 2010 misoprostol-only cohorts were gestational age at initiation of abortion (median (interquartile range): 18.1 weeks (17.6-19.9) and 16.5 weeks (14.9-17.6) respectively; and the proportion reporting prior abortions (7% [5/74] in 2008 compared to none in 2010). Participant characteristics for the combined 2008/2010 misoprostol group and the mifepristone group are shown in Table 7.1. There were no significant differences between the combined misoprostol-only group and the mifepristone group for age, education, formal housing, paid work, home language, parity or prior vaginal delivery. More participants receiving mifepristone reported prior abortions and median gestational age on admission was 1 week later than the misoprostol-only group (Table 7.1).

Table 7.1 Participant characteristics by medication regimen.

Characteristic	2008/2010 misoprostol-only	2014 mifepristone-misoprostol	p-value*
Age (years)	n=142	n=208	
18-25	77 (54%)	94 (45%)	0.373
26-35	53 (37%)	92 (44%)	
>35	12 (8%)	22 (11%)	
High school education	n=129‡	n=208	
Completed Grade 12	62 (48%)	98 (47%)	0.477
Home language	n = 138#	n=208	
Xhosa	86 (62%)	151 (73%)	0.118
English	26 (19%)	22 (11%)	
Afrikaans	17 (12%)	25 (12%)	
Other	9 (7%)	10 (5%)	
Employment	n=129‡	n=208	
Paid work	50 (39%)	80 (39%)	0.523
Parity	n=142	n=208	
Nulliparous	26 (18%)	41 (20%)	0.428
Prior vaginal delivery	n=129‡	n=208	
	95 (74%)	144 (69%)	0.229
Prior abortion	n=129‡	n=208	
	5 (4%)	21 (10%)	0.027
Gestational age (weeks)**	n=142	n=208	
12.1-16.0	36 (25%)	30 (14%)	<0.001
16.1-18.0	54 (38%)	55 (26%)	
18.1-20.0	52 (37%)	123 (59%)	

*p-value for chi squared tests of differences between misoprostol-only and mifepristone-misoprostol groups.

‡13 records with missing data #4 records with missing data.

**Gestational age at abortion commencement. Date of first misoprostol for 2008 and 2010 cohorts, and date of mifepristone for 2014 cohort.

7.4.2 Drug Administration

All women in the mifepristone cohort were instructed to self-administer 200 mg mifepristone orally at home, 24-48 hours prior to their booked admission date. Women with gestations within 1-2 days of the legal limits for medical abortion were given priority bookings, and admission was arranged in order to manage bed availability. Only 1 participant was admitted directly following assessment for mifepristone administration in

the hospital, as her travel time home and back would have been excessive. The median and inter-quartile range (IQR) for the mifepristone-misoprostol interval was 49 hours (IQR 4-53). Intervals were <48 hours for 44% (91/208) participants and >72 hours for 2% (4/208). All participants reported they took the mifepristone at home, and none aborted prior to hospital admission.

Following admission, administration of misoprostol was incorporated into the general ward routine. Misoprostol doses and administration routes are shown in Table 7.2. Although there was an attempt to standardize the protocol, dosage regimens sometimes differed across facilities, or according to physician preference in certain situations, such as with prior caesarean section. Generally, misoprostol-alone cohorts received an initial dose of 600 mcg, with 21% (28/135) receiving 400 or 200 mcg. Administration routes were mostly vaginal (PV) (84%, 113/135), with a minority receiving either oral or sublingual administration. Subsequent dosing was 400 mcg at 3- or 4-hourly intervals. If no expulsion had occurred after 13 doses, following a rest period, misoprostol was started again. If expulsion did not occur, other prostaglandins were used. For the combined mifepristone-misoprostol regimen the first misoprostol dose was generally 800 mcg administered PV, with 24% (49/208) receiving either 400 mcg orally or 600 mcg PV or by the sublingual route. Subsequent dosing was mostly 400 mcg orally, with 7% (13/208) sublingually, up to 10 doses if needed, sometimes followed by a rest period. The median total dose of misoprostol and the median number of misoprostol doses were less in the mifepristone cohort (1600 mcg vs. 1800 mcg; 2 vs. 3, $p<0.001$).

Table 7.2 Misoprostol dosage regimen.

Misoprostol regimen	2008/2010	2014
Dosage of 1st misoprostol	n=135‡	n=208
200 mcg	2 (1.5%)	0 (0%)
400 mcg	26 (19.3%)	13 (6.3%)
600 mcg	107 (79.3%)	36 (17.3%)
800 mcg	0 (0%)	159 (76.4%)
Route of administration of 1st dose	n=135‡	n=208
Vaginal	113 (83.7%)	178 (85.6%)
Oral	20 (14.8%)	13 (6.3%)
Sublingual	2 (1.5%)	17 (8.2%)
Dosage of 2nd misoprostol	n=133‡	n=191
200 mcg	11 (8.3%)	0 (0%)
400 mcg	120 (90.2%)	179 (93.7%)
600 mcg	2 (1.5%)	12 (6.3%)
800 mcg	0 (0%)	0 (0%)
Route of administration of 2nd dose	n=133‡	n=191
Vaginal	1 (0.8%)	0 (0%)
Oral	130 (97.7%)	178 (93.2%)
Sublingual	2 (1.5%)	13 (6.8%)
Total misoprostol dosage (mcg) Median (IQR) p<0.001*	1800 (1400-2400)	1600 (1200-2000)
Number of misoprostol doses Median (IQR) p<0.001*	4 (4-6)	3 (2-4)

*p-value of Kruskal-Wallis test for median differences between misoprostol-only and mifepristone-misoprostol groups.

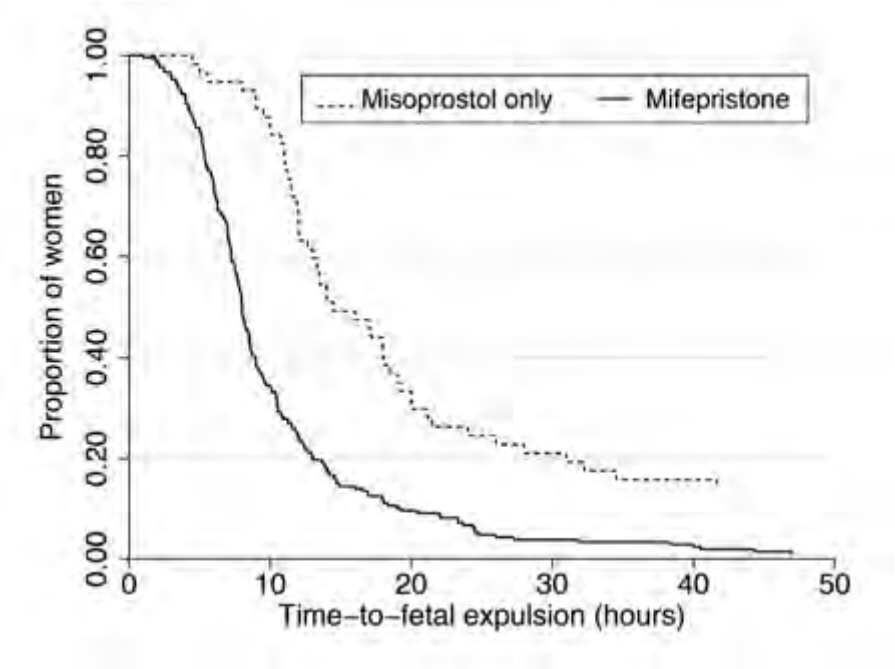
‡7 records with missing data.

7.4.3 Clinical outcomes

Fetal expulsion occurred in all participants except one in the 2008 misoprostol-only cohort, who was transferred to another facility for D&E. Median time-to-fetal expulsion was shorter (8.0 vs. 14.5 hours; p<0.001), and the proportion with fetal expulsion within 24 hours higher (93% [194/208] vs. 77% [44/57]; p<0.001) for the mifepristone cohort compared to the misoprostol-only 2010 cohort. Kaplan-Meier survival curves and log rank tests for unadjusted time-to-fetal expulsion demonstrated significantly shortened intervals for the mifepristone cohort (p<0.001, Fig 7.2). Hazard ratios for fetal expulsion from Cox proportional models adjusted for gestational age, prior abortion and prior vaginal delivery and stratified by quartiles of total misoprostol dose were significantly higher for the

mifepristone group, overall and for the PV subgroup (p<0.05 for all strata, Supplementary Table 7.5).

Figure 7.2 Time-to-fetal expulsion (unadjusted) for 2010 misoprostol-only (n=57) and mifepristone groups (n=208).



Uterine evacuation of placental tissue was performed according to physicians' judgement, and there was higher rate of uterine evacuation of placental tissue among the mifepristone group over the misoprostol-only group (76% [159/208] vs. 58% [82/142]; p<0.001, Table 7.3). Methods used were curettage in the 2008/2010 cohorts and vacuum aspiration or curettage for the mifepristone group. Despite higher evacuation rates, median time-to-abortion completion, which includes time to completion of uterine evacuation, if performed, was significantly shorter in the mifepristone group (11.1 vs. 24.8 hours; p<0.001) compared to misoprostol only and a significantly higher proportion had completed their abortion within 24 hours (88% [177/208] vs. 46% [62/134]; p<0.001, Table 7.3).

Table 7.3 Procedure details and clinical outcomes. 2008/2010 - misoprostol only. 2014 - mifepristone misoprostol.

Clinical outcomes	2008/2010	2014	p-value*
Time from 1st dose misoprostol to fetal expulsion	n=57‡	n=208	<0.001
Median (IQR) (hours)	14.5 (11.5-24.0)‡	8.0 (6.0-11.9)	<0.001
Fetal expulsion <24 hours	n=57‡	n=208	
n (%)	44 (77%)‡	194 (93%)	<0.001
Uterine evacuation performed	n=142	n=208	
n (%)	82 (58%)	159 (76%)	<0.001
Time from 1st dose of misoprostol to abortion completion**	n=134#	n=208	<0.001
Median (IQR) (hours)	24.8 (17.8-37.6)	11.1 (8.7-17.0)	
Complete abortion <24 hours	n=134#	n=208	<0.001
n (%)	62 (46%)	177 (88%)	
Hospitalization	n=142	n=208	
Same day discharge	1 (1%)	0 (0%)	<0.001
1 night	62 (43%)	161 (77%)	
≥2 nights	80 (56%)	47 (23%)	
Analgesia given	n=142	n=208	
n (%)	63 (44%)	173 (83%)	<0.001
Major complications	n=142	n=208	
n (%)	11 (8%)	12 (6%)	0.791
Haemorrhage requiring transfusion	8 (6%)	9 (4%)	
Infection treated with IV antibiotics	3 (2%)	2 (1%)	
Possible seizure	0 (0%)	1 (<1%)	
Received post-abortion family planning	n=127***	n=206 §	
n (%)	125 (98%)	204 (99%)	0.623
Injectable	111 (87%)	139 (67%)	
Oral contraceptives	9 (7%)	4 (2%)	
Intrauterine device	5 (4%)	19 (9%)	
Implant	0 (0%)	42 (20%)	

*p-value of Chi-squared tests for differences between misoprostol-only and mifepristone-misoprostol groups. ‡Data only recorded for 2010 cohort, 1 record with missing data. **Abortion completion defined as either placental expulsion if no surgery or surgery. #8 records with missing data, § 2 records with missing data, *** 15 records with missing data

Duration of hospitalization was significantly shorter for the mifepristone group (77% [161/208] vs. 44 % [62/142] staying one night or less; p<0.001). The rate of major complications was similar for the two groups (6% [12/208] vs. 8% [11/142]; p=0.791). Complications included hemorrhage requiring blood transfusion, infection treated with IV antibiotics and possible seizure (Table 7.3). All these complications were identified during hospitalization except for one in the mifepristone cohort, which was identified at the follow-up call. More women received analgesia in the mifepristone compared to the misoprostol groups (83% [173/208] vs. 44% [63/142]; p<0.001). Almost all participants in both mifepristone and misoprostol-only groups (99% [204/208] and 98% 125/127]; p=0.623) received a family planning method post-abortion. The most common method in both groups was the injectable (67% [139/204] vs. 87% [111/125]), with a shift towards the implant (introduced into the public sector in 2013) in the mifepristone group (20% [42/204]).

7.4.4 Women's experiences

More participants in the mifepristone group experienced nausea (55% [112/205] vs. 22% [29/129]; p<0.001), vomiting (45% [92/205] vs. 27% [35/129]; p<0.001) and tiredness (76% [155/203] vs. 56% [72/129]; p<0.001). Other symptoms experienced similarly by both mifepristone and misoprostol-only groups, respectively, were diarrhea (58% [119/205] vs. 62% [80/129]; p=0.472), dizziness (41% [85/205] vs. 40% [52/129]; p=0.835) and headache (35% [72/203] vs. 37%, [48/129]; p=0.441). There was no significant linear association between pain levels and groups (Table 7.4); however, fewer women in the mifepristone compared to the misoprostol group experienced extreme pain compared to other levels of pain (13% [26/205 vs. 41% [53/129]; p<0.001). Trends in overall satisfaction were similar for both group, while more reported they would recommend the abortion method to a friend in the mifepristone group (Table 7.4; p<0.001).

Table 7.4 Women's experiences of the abortion.

	2008/2010	**2014**	**p-value***
Overall pain during abortion experience	n =129 ‡	n=205#	
Extreme pain	53 (41%)	26 (13%)	0.320
High pain	23 (18%)	108 (53%)	

Moderate pain	19 (15%)	64 (31%)	
Slight pain	14 (11%)	18 (8%)	
No pain	20 (16%)	2 (1%)	
Overall satisfaction with abortion	n =129 ‡	n=205#	
Very or somewhat satisfied	117 (91%)	195 (95%)	0.127
Neutral	8 (6%)	3 (2%)	
Somewhat or very dissatisfied	4 (3%)	7 (3%)	
Would recommend the abortion method to a friend who needed one at same gestational age	n =129 ‡	n=205#	
Highly or somewhat agree	90 (70%)	183 (89%)	<0.001
Neutral	4 (3%)	1 (0.5%)	
Somewhat or highly disagree	35 (7%)	21 (10%)	

*p-value for chi squared test for trend of linear association between groups and levels of outcome

‡13 records with missing, #3 records with missing data.

7.5 Discussion

Compared to the previous misoprostol-only regimen, the new service regimen reduced time-to-abortion events and hospitalization. The 93% fetal expulsion rate within 24 hours in our mifepristone group is slightly lower compared to the 94-98% reported in RCTs and case series (15, 16, 22-24). It is possible that the variability of the mifepristone-misoprostol interval in our study (range; 27 – 77 hours) contributed to the marginally lower expulsion rate compared to these studies. In addition, the dosing and route of administration of misoprostol in our 2014 mifepristone group was not wholly consistent with the WHO evidence-based clinical guidelines for mifepristone in combination with misoprostol, which advise 800 mcg vaginally, followed by 400 mcg vaginally or sublingual, q 3 hrs., and 400mcg vaginally or sublingual, repeated q 3 hrs. for misoprostol only (35). This may also have contributed to the slightly lower 24-hour expulsion rates than reported elsewhere. Deviations from WHO protocol were due to physician preference in cases with prior caesarean section, and the use of the oral route for the second misoprostol dose is in accordance with Royal College of Obstetricians and Gynaecologists (RCOG) guidance, which has been followed in other settings (23).

Other research has reported much lower rates of placental retention for second-trimester medical abortion with mifepristone (16), and our finding of a higher surgical evacuation rate with the mifepristone regimen is likely to be specific to the service delivery setting. In both

study groups time-to-abortion completion may have been extended due to lack of operating theatre availability when uterine evacuation was performed, which was facility-dependent. The high rate of evacuation, especially in the mifepristone group, may be related to the introduction of the new service in teaching facilities with a high rotation of junior doctors. This may have also contributed to the shorter time-to-abortion completion in this group. Routine use of evacuation varies across settings and institutions (13, 36); however, it is acknowledged that clinical experience in assessment of abortion completion and manual assistance with placental expulsion is needed to avoid this practice (13). Further training of health professionals in this regard has been implemented in our study facilities.

The introduction of self-administration of mifepristone at home prior to admission for second-trimester medical abortion allowed for planning for admission while eliminating additional hospital visits for mifepristone where admission was delayed by more than 48 hours. Although women's convenience was not specifically catered to in this study, flexible timing of admission without requiring mifepristone to be taken on-site gives women time to arrange their personal affairs, if needed, and we consider it a beneficial service delivery option. Most women stayed at least one night in hospital as incorporation of abortion care into the general ward routine delayed women receiving their misoprostol while this study was in progress. To facilitate same-day discharge, a day ward administering misoprostol immediately at early morning admission is recommended as the most cost-effective model of service provision for medical abortion (13, 36). This was considered feasible in China and Europe (15, 23, 37), and was recently implemented at hospital C (personal communication, MP, 2015). It is expected that the new regimen may reduce costs per woman served, which we plan to explore in a future analysis.

The number of women experiencing hemorrhage requiring transfusion was similar in both the mifepristone and misoprostol-only groups and (Table 7.3). The proportion in the mifepristone group (4.3%) was comparable to the 4% rate reported previously for all deliveries in a South African hospital in 2010 (38), but higher than other studies on second-trimester medical abortion, which vary from 0.7-3% (16, 23, 24). The transfusion threshold is context- and provider-dependent, and most women having transfusions had a documented drop in hemoglobin with signs and/or symptoms of anemia. Possible reasons

for this higher rate of transfusion could be a high rate of baseline anemia, or the high HIV prevalence; nonetheless, interventions to reduce transfusion should be explored in future research. For other major complications, of the 5 cases with infections requiring IV antibiotics, 4 were detected during admission. While seemingly of different origin, the 1% infection rate in this study is comparable to that (8/1002) reported elsewhere at 2-week follow-up (23).

In terms of women's experiences, both the mifepristone and the misoprostol-only groups reported a high prevalence of common side effects. The greater proportion in the mifepristone group experiencing nausea, vomiting and tiredness may be due to the higher initial dose of misoprostol, or possibly to mifepristone. In contrast, this group also reported less extreme pain levels and more received analgesia than the misoprostol-only cohorts; however, pain levels in all groups remained high, and more research on pain management is needed to better guide practice. The improved acceptability in the mifepristone group, despite the higher proportion who underwent curettage for retained placental tissue, is encouraging. Reduced hospitalization and less extreme pain may have contributed to a better experience. However, unmeasured differences between facilities and over time may also have played a part, and we cannot make conclusive statements in this regard from our data.

Limitations of this study are that the majority of participants in the mifepristone cohort groups were from a different facility from the historic cohorts due to changes in service delivery. Study groups were non-randomized. For example, gestational age was different in the two groups; however, we adjusted for known confounders, including gestational age, in the proportional hazards analysis (Supplementary Table 7.5). The comparison for time-to-fetal expulsion may have been underpowered due to the missing data in the 2008 cohort; nonetheless our study findings were statistically and clinically significant. The participant numbers were unbalanced between the two centers in all cohorts as Hospital B is a smaller site; however, proportions relative to the overall caseload for each center were consistent over the three phases of data collection. In addition, the study extended over six years of service provision, during which unmeasured confounding factors may have been influenced our findings. We did not conduct follow-up interviews for either of the misoprostol-only

cohorts; however, the chart reviews were done subsequent to discharge, thus it is unlikely that we have underestimated major complications for this group. There may have been some social desirability bias, however this would not have differed between the study groups. The initial misoprostol dosages differed between the study groups, but they were generally consistent with WHO guidance, which recommends a lower dose for the misoprostol-only second-trimester regimen (35). To take this into account, we stratified the proportional hazards analysis according to categories of overall misoprostol dosage (Supplementary Table 7.5). The misoprostol dosages sometimes differed from recommended regimens; however, in this observational study we aimed to observe real-world outcomes after implementing this new service. Finally, our findings are specific to the South African context where second-trimester medical abortion is performed in secondary level hospitals and may not be generalizable to other settings.

7.6 Conclusions

This study reports clinical and acceptability improvements during introduction of a mifepristone-misoprostol regimen for medical abortion at 12-20 weeks gestational age at busy public sector hospitals in South Africa. Specific aspects that were successful included self-administration at home of mifepristone which allowed for admission planning, shortened procedure times, reduced hospitalization which increased the capacity of facilities to serve more women compared to previously, and increased acceptability.

7.7 Acknowledgments

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Table 7.5 Supplementary Table: Hazard ratios for mifepristone-misoprostol compared to misoprostol only

Stratified by misoprostol dose and adjusted for gestational age at abortion commencement, prior vaginal delivery and prior abortion.

	Time-to-fetal expulsion	
	All n=263†	PV route 1st misoprostol dose n=221
Misoprostol dose (mcg)	HR (95%CI)	HR (95%CI)
600-1200	n=89 3.1 (1.7-5.3) p<0.001	n=59 3.6 (1.4-9.3) p=0.008
1400-1600	n=78 10.8 (3.9-29.7) p<0.001	n=77 29.6 (6.4-136.9) p<0.001
1800-2200	n=43 6.8 (2.4-19.0) p<0.001	n=40 10 (2.2-48.2 p=0.003
2400-14600	n=53 3.8 (1.6-8.9) p=0.002	n=45 3.0 (1.2-7.7) p=0.021

†Data only recorded for 2010 cohort; 3 records with missing data for at least 1 variable in the model.

Chapter 8 Discussion, Recommendations and Conclusions

8.1 Introduction

This thesis evaluated interventions and strategies to strengthen MA access and provision in the South African public sector following the introduction of mifepristone into service delivery protocols. Four studies addressed the thesis overall aim by investigating key research questions as outlined in Chapter 1. Questions 1 to 3 each related to a specific subtask for MA in the first trimester, as identified by the WHO: estimation of gestational age for women seeking abortion (question 1); self-administration of misoprostol and self-management of medical abortion at home (question 2); and self-assessment of medical abortion outcome (question 3). Question 4 related to clinical outcomes and women's experiences of public sector second trimester MA care following the introduction of mifepristone into the service. Studies 1 through 3 examined the feasibility, safety, acceptability and effectiveness of interventions to support task sharing or self-management for each of the component tasks of first trimester MA. Study 4 evaluated the new second trimester MA service in which mifepristone is self-administered by women, followed by in-facility care, task shared between nurses and doctors.

Prior to these studies, limited research had been published on task sharing MA with mifepristone in the public sector in South Africa. Instead, South African studies on MA were aimed at guiding policy decisions, documenting the potential for integrating MA with mifepristone into existing first trimester public sector surgical abortion services (1-3) and evaluating second trimester MA service (4, 5). Task sharing in MA was explored in the multi-country parent study to Study 1 (this thesis), and indicated successes as well as challenges for eligibility assessment for MA by CHWs (6, 7). In addition, a recent pilot study showed promising results for an online tool for self-assessment by women of eligibility for MA (8).

This chapter includes a summary and interpretation of the findings, addresses strengths and limitations of the work overall, and explores some key cross-cutting issues that emerged from the overall results. Recommendations are made for future research and the thesis ends by presenting a set of overall conclusions.

8.1.1 Summary of findings and interpretations

Paper 1 (Chapter 3) determined criteria identifying women for whom LMP dating could safely be used for screening and referral purposes, with a view to task sharing this activity. The percentage of incorrect assessments was higher than in developed country settings (9), but results were still encouraging. Generally, both nurse-clinicians and CHWs were supportive of task sharing screening and referral for medical abortion, but felt that ultimately nurse-clinicians should determine eligibility based on clinical findings. Between nurse-clinicians and CHWs there were some divergent opinions on the "where" and the "how" that task sharing could best be put into practice.

The second paper (Chapter 4) evaluated the effectiveness and acceptability of timed text messages (mHealth) to provide guidance and support to women while self-administering misoprostol and self-managing their abortion procedure at home. The intervention had a small but statistically significant effect in decreasing women's anxiety over this period, reduced their stress levels and better prepared them for the bleeding, pain and other side effects they experienced. The text messages were also highly acceptable to women; the paper co-authored by the candidate (not incorporated in this thesis) reported that the messages served as useful reminders of symptoms of a safe successful abortion as well as signs of complications, provided reassurance and imparted a sense of support (10).

Studies 2 and 3 evaluated two different modalities for self-assessment of medical abortion outcome (reported in Papers 3 and 4, respectively). In Study 2, the intervention group used their mobile phones to complete an automated interactive questionnaire on the abortion symptoms they had experienced, to establish the outcome of their procedure. This approach proved feasible, as most women successfully completed the mobile phone questionnaire, however the study concluded that clinical history alone could not be recommended for self-assessment.

Study 3 was designed with the results of Study 2 mind. The self-assessment package included a LSUPT and symptom checklist, and was supplemented by timed text messages similar to those used in Study 2. In Study 3, women were randomized to a demonstration group or an instruction-only group when guided on how to perform and interpret the test.

Of the three women (0.7%) assessed by providers to have ongoing pregnancies, one from the demonstration group reported a negative LSUPT at follow-up 14 days post-mifepristone. Result were inconclusive in terms of non-inferiority for instruction-only; however as found in with other settings, most women found the pregnancy test easy to do and preferred self-assessment to in-clinic follow-up. (11-15).

In both Study 2 and Study 3, the rate of ongoing pregnancies was within the expected range (0.5% and 0.7% respectively). Yet additional treatment for incomplete abortion was provided significantly more frequently to women in Study 2 (29% vs. 9%), suggesting an unnecessary level of intervention by providers. Neither study interrogated this directly, however MA in the public sector had been recently introduced at the time of Study 2, but had been operational for four years during Study 3. In addition, Study 3 was preceded by a clinical mentoring intervention for providers on dispensing with routine ultrasound and avoiding of unnecessary additional treatment at follow-up. It is likely that greater familiarity with the method reduced unnecessary interventions at follow-up however this was still higher in Study 3 than other LMIC settings (11, 12, 15, 16).

Study 4 (Paper 5) documented clinical outcomes and women's experiences of medical abortion in the second trimester following the introduction of mifepristone into the service in 2013/2014, compared to historic cohorts receiving misoprostol only. In the new service, following assessment by physicians, women were issued with 200mg mifepristone to be self-administered 24-48 hours prior to their scheduled admission. As per the WHO guidance on task sharing for abortion care (17), registered and assistant nurses monitored and cared for women from the first misoprostol dose to completion of their procedure, although doctors were available if needed. In line with findings globally, times to abortion were significantly shorter for women receiving mifepristone and fewer experienced extreme pain, more found their abortion method acceptable although the severity of some other side effects from the medications were increased. Over all cohorts, the rate of major complications was unchanged, however uterine evacuation for placental tissue was more frequently performed in the new service. Despite this, the hospital stay was shortened for this group. The high rate of evacuation has since been addressed at facility level and is much reduced, following additional training and input from specialist doctors (In depth interview,

OBGYN registrar, Hospital A. 12 March, 2015). Increasing familiarity of doctors and nurses with second trimester medical abortion and persistent efforts to avoid unnecessary evacuations have reduced this practice in other settings (18). As the service becomes regularized, experienced senior nurses involved with the service may be best-placed to guide assessment in this regard (personal communication, OBGYN Specialist, European Society for Contraception and Reproductive Health meeting, May 2016).

8.2 Strengths and limitations of the research

Study-specific strengths and limitations have been addressed in each chapter (3 – 7); however, relevant additional considerations and some cross-cutting issues are discussed further in the following section.

8.2.1 Study design

The bearing of the various study designs in this thesis on the reliability of the findings deserves mention when considering all five studies together. The cross sectional design of Study 1 was appropriate as both community health workers and nurse-clinicians assessed each woman's GA on the same day. CHWs estimated women's GA prior to nurse-clinicians completing the ultrasound examination, and nurse-clinicians were blinded to CHWs GA assessment. The RCT design of Studies 2 and 3 contributed rigor and certainty to the findings, given the strength of the RCTs design for clinical research comparing treatment effects. In Study 2, the one of the main outcomes, the feasibility of using mobile phones to complete a questionnaire, was reliably established from analysis of the full computer log. However, as the self-assessment by mobile was conducted some days before the provider assessment, this could have adversely impacted on the specificity of the self-assessment for women whose symptoms progressed in the intervening days.

Study 4 used a pragmatic study design, comparing results from repeated cross sectional studies. The aim was to document service delivery changes rather than drug efficacy, and as such the use of historic cohorts in the analysis could be justified. Nonetheless, unmeasured confounding and selection bias are inherent in this approach. As noted in the paper, stratification and adjusting the hazard ratios for measured covariates was done to limit this where possible.

8.2.2 Sample size

Study 1 quantitative component was a sub-study, with the sample size based on the parent validation study. The study was adequately powered for the analysis performed, but insufficient to perform a multivariable analysis of associations with the caution zone, and it was recommended that larger studies be undertaken to identify these factors. In Study 2, the sample was adequate to generate conclusive results for the main outcomes, however neither Study 2 nor Study 3 were powered to assess validity of the self-assessment for ongoing pregnancy. Although the most important outcome, it must be noted that few published studies have managed this, given that it is such a rare event (19). Published studies validating self-assessment for ongoing pregnancy used estimated rates of 1.2% to 2%, necessitating samples of 1433 and 2400 respectively (12, 15). Studies this large would have incurred higher costs than resources allowed for in this thesis. Other non-inferiority RCTs evaluating self-assessment using LSUPTs did not validate self-assessment against provider assessment for each participant, but attempted to trace participants over extended follow-up periods for detection of ongoing pregnancy from facility records or by phone (11, 13). However, it is unlikely that these long term follow-up strategies would have been successful in our studies, as women could have attended other facilities and changes in mobile phone numbers are common over long periods of time.

Study 4 based the sample size required for the mifepristone group on fetal expulsion rates from the reported literature and from the 2010 historic cohort where time of fetal expulsion was recorded. The 2008 and 2010 historic cohorts were from observational studies, each conducted over approximately 6 months of service provision, and sample size for these cohorts was not pre-defined by calculation. The presence of confounders such as gestational age of women and differences in dosage regimens necessitated a stratified analysis and some strata have low numbers. Despite the limitations of Study 4, sample sizes were adequate for comparison of the important outcomes.

8.2.3 Internal validity

As already noted in Studies 2 and 3, there is potential for bias where differential LTF occurs, where main outcomes are evaluated at clinic follow-up and no active tracing is done. LTF is a well-known difficulty encountered in abortion research as most women do not wish for

further discussion relating to their procedure, and active tracing is made more difficult by change in phone numbers if follow-up is extended over long periods of time. In Study 2 fewer women were LTF from the intervention (SOC+mobile) arm. However, significant bias was unlikely as a comparison of baseline characteristics within each study arm of those LTF and those returning within each study arm showed no significant differences. In Study 3, the sensitivity analysis with those LTF classified as accurate self-assessment and then classified into inaccurate self-assessment did not alter results, adding rigor to the primary analysis.

8.2.4 External validity

The external validity of the overall findings in this research may be subject to some limitations due to the inclusion of NGO facilities which are accessed by women with generally higher living standards than the national average. Recent indicators for South African women aged 20+ in 2014 showed that 28% had completed grade 12, 52% were employed and 77% of all households lived in formal housing (20). In Studies 1 and 2, all (Study 1) or some (Study 2) participants were recruited from urban or peri-urban NGO reproductive health-care facilities, were better educated, had a higher employment rate and more lived in formal housing compared to the national average. Even so, Study 1 findings show similarities to those from an earlier study (2007) conducted in South African public sector facilities in three provinces (21), and a measure of validity of the text message interventions for the South African public sector context is inferred from similar findings for women's acceptability in both Study 2 and Study 3, the latter of which was done in the public sector.

Nonetheless, generalizability across South Africa at this point in time may be limited by the disparity in service provision across provinces. Except in Study 1, the study facilities in this research were located in the Western Cape, where public sector health-care is considered to out-perform other provinces. The Western Cape led the formulation of local guidelines for incorporating mifepristone into service delivery and the introduction of mifepristone into facilities (initially stewarded by Medicins Sans Frontiers). Current service statistics indicate that abortion is provided in all provinces, but that first trimester MA services are only operational in six of the nine provinces (personal communication, NGO country director; 21 January 2016), and are still mainly provided in centrally located hospitals. Thus,

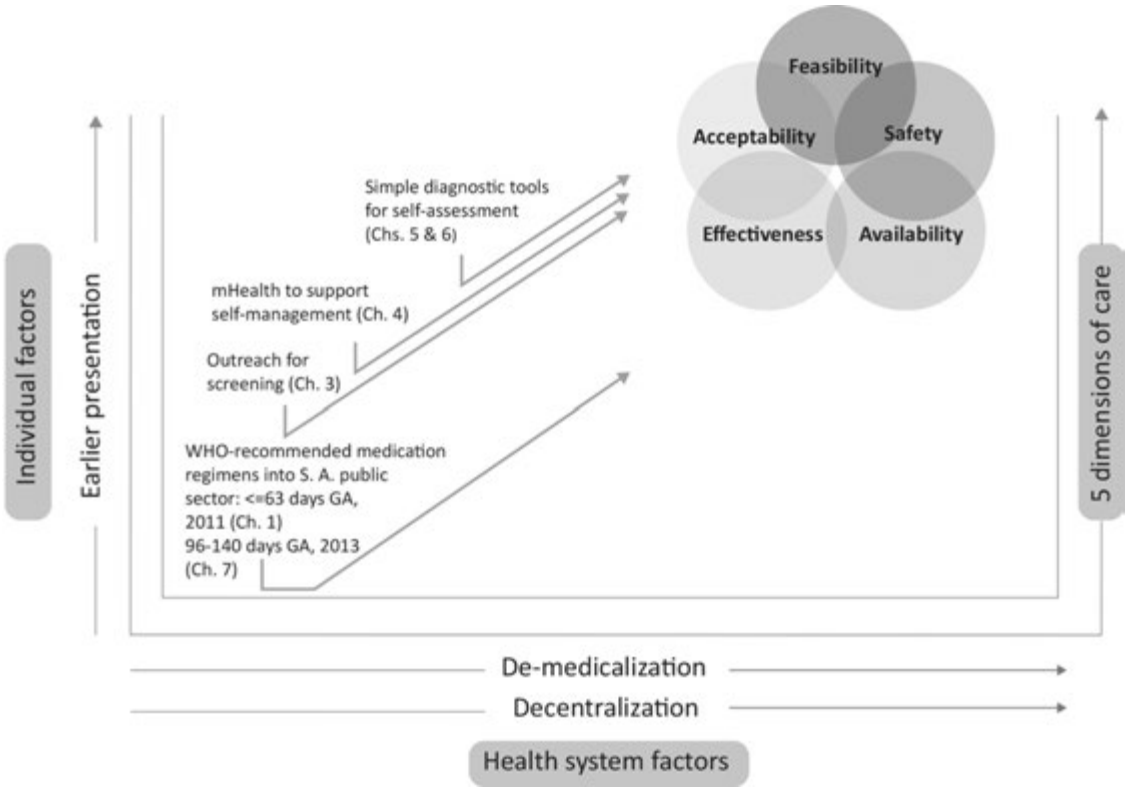
it must be cautioned that as South Africa is highly unequal in distribution of services and wealth, the interventions may need modification for implementation in the more under-resourced regions. For Study 4 however, the results present much-needed evidence that can be used to strengthen second trimester services in the remainder of the country.

When considering other LMIC settings, the results from Studies 1, 3 and 4 have similarities with findings from these contexts (6, 11, 12, 15, 22), where mifepristone is registered for use but this regimen for abortion care is not readily accessible. In addition, evidence is emerging for other LMICs from a Colombian-based study using a similar text message intervention among women undergoing MA (Gerdts, C et al. Manuscript in preparation, 20/08/2106.

8.3 Emerging issues and implications for health care delivery

The following sections of this chapter include a broader discussion of the studies overall, as framed by the thesis conceptual framework described in Chapter1. The framework is revisited below (Fig. 8.1) with the relevant thesis chapters inserted into the figure so as to map the studies onto the concepts in a concrete manner.

Figure 8.1 Thesis conceptual framework: enabling factors for strengthening health-care



Specific issues that will be further discussed in following sections include:

- De-medicalization, decentralization and safety in medical abortion care
- Autonomy and abortion self-management: meaning and perspectives
- The place of mHealth for abortion care in the mHealth domain
- Potential new approaches for abortion and implications for abortion service delivery in the South African context
- Recommendations for further research and conclusions

8.4 De-medicalization, decentralization and safety in medical abortion care

De-medicalization and decentralization (defined in the Glossary of Terms) are distinct but overlapping approaches to service delivery, both with the same goal of increasing access and stream-lining health-care. In this thesis, de-medicalization in practical terms translates into self-management. The following section discusses de-medicalization and decentralization, from the perspective of providing safe abortion care.

8.4.1 The spectrum of de-medicalization

To develop overall recommendations and conclusions from the findings in this thesis, it is useful to review provision of medical abortion care along a spectrum from a highly medicalized approach to a less medicalized approach, as recently proposed (23). There have been important shifts across this spectrum since medical abortion with mifepristone was first introduced in 1998, following the protocol formulated by Swahn and Bygdeman (24). Prior to this, modern recommended methods involved surgery and abortion care was necessarily highly medicalized to ensure provision of safe abortion care and, by law, procedures had to be done in a designated or approved facility. When mifepristone combined with a prostaglandin analogue was first introduced in Western Europe, medical abortion involved an extended and onerous 3 or 4-visit process. The initial visit was limited to assessment and counselling; at visit 2 women took mifepristone under observation; at visit 3 they took the misoprostol and had to remain in the clinic under observation until expulsion; and the final follow-up clinic visit was to assess the abortion outcome and provide contraception (23). Based on evidence demonstrating safety and acceptability (25), in some countries this was reduced to a 3-visit model where assessment, counseling and taking mifepristone under observation was done at visit 1. At visit 2 women returned to the clinic to receive their misoprostol, but could self-administer the pills at home. A final follow-up visit for assessment and contraception was required. In some countries, the process was further streamlined when health regulatory authorities elected to interpret the law such that medical abortion is performed when mifepristone is swallowed, which must be done in the clinic. This meant that women could self-administer their misoprostol at home and simplified MA care to a 2-visit process for routine cases. However, this is not currently permitted in France and the UK, and women still have to return to the clinic for observed administration of misoprostol (26) (personal communication, KGD, 23 June 2016).

The 2-visit protocol was adopted in many other settings, notably in the US, but only in states that did not require providers to follow the FDA approved labelling of 2000 (27), as well as in many developing and resource-constrained settings where MA with mifepristone and misoprostol was being introduced, including South Africa. In South Africa, the first trimester MA service model of 2010 for the Western Cape public sector recommended an initial visit at a primary care facility for assessment, counselling and referral, directly-observed

mifepristone ingestion and provision of misoprostol for self-administration (with an option for in-clinic administration, if preferred), and stressed the importance of a follow-up visit 2 - 3 weeks later for abortion assessment and contraception provision (28). While offering a more streamlined approach than early MA protocols, this protocol still reflected a largely medicalized approach. In addition, as noted in the literature review, operational facilities were initially confined to centralized locations in South Africa and the service was slow to expand more broadly into other primary care facilities (Study 1). As most women access the health system through primary care facilities that do not provide MA, at the time of the research in this thesis, MA usually involved at least three clinic visits. Studies in this thesis were designed to simplify service delivery offered within this 2010 service model, with a view to facilitating access, supporting self-management during the home phase of the abortion and replacing the requirement for in-clinic follow-up with a self-assessment.

A global shift towards a more de-medicalized approach has been rapidly gaining ground in recent years, incorporating task sharing with CHWs and self-management by women, as well as flexibility and choice. In other areas of health care, dropping follow-up requirements has been seen as a positive development (29, 30), and in MA, self-management can increase access, reduce demand on the health care system and help to overcome financial and geographical barriers (22). However, self-management of abortion is not without some risk, and is not necessarily fully acceptable or feasible in all settings. The interventions evaluated in Studies 2 and 3 are strategies aimed at mitigating risk while strengthening acceptability of abortion care that incorporates more self-management.

8.4.2 De-medicalization and safe abortion care

From a public health perspective, self-management of abortion processes can only be recommended if safety of abortion care is not compromised. Taking safety into account, the WHO does not make a recommendation with respect to self-managing the overall medical abortion process, due to insufficient evidence on self-managing all thee subtasks together (17). For the individual tasks, the recommendations for self-managing are for pregnancy durations up to 63 days, and the recommendations on self-assessment of outcome are for mifepristone-misoprostol rather than misoprostol alone regimens (17). However, the new developments favoring increased self-management and task sharing in medical abortion

care prompted review of the earlier WHO definition of unsafe abortion (31, 32). Formulated in 1992, The WHO defined unsafe abortion as “A procedure for terminating a pregnancy performed by persons lacking the necessary skills or in an environment not in conformity with minimal medical standards, or both.” More recently, the WHO noted that “The persons, skills and medical standards considered safe are different for medical and surgical abortion and also depend on the duration of the pregnancy” and that safety must be interpreted in line with most recent technical guidelines (31). Self-management approaches are thus only recommended where women have access to appropriate information and to health services, if needed (17).

At what point along the spectrum of self-management of abortion becomes unsafe requires careful and ongoing evaluation. Small risks related to each of the subtasks will be cumulative where there is no interaction with the health system. For example, if a woman’s GA is significantly underestimated from her LMP date, there is a higher risk of ongoing pregnancy as she may not receive an effective misoprostol dose. If she then self-manages her MA at home but self-assesses the MA incorrectly as successful, her pregnancy could have advanced into the second trimester by the time she clearly recognizes her situation. Fear, denial and confusion may also contribute to this delay, but can be ameliorated by strengthening pre-abortion counseling by providers and strengthening women’s understanding and providing reassurance through the use of mHealth or helplines.

From an alternative perspective, researchers have questioned cautious approaches that require initial in-clinic assessment (33) and fully sensitive or predictive self-assessment tools. Since all ongoing pregnancies will eventually be detected and do not pose a critical health risk, and any follow-up requirement is burdensome and no longer standard care for many other types of medical procedure, this viewpoint argues that women should be given the option of determining the need for follow-up themselves (14, 19) without having to wait on the emergence of scientific evidence for a risk-free solution.

In this thesis, the research findings partially support the extent of medicalization in the new revised 2016 Western Cape guideline, although new approaches exploring new roles are recommended to create the opportunity for more flexible and accessible care. Additional

risk management using mobile phone technology or hotlines and the assurance of reliable, timely access to health-care professionals, if needed as well as the certainty of obtaining care for failed procedure are requirements should go a long way to ensure safe and more widely accessible abortion care.

8.4.3 Decentralization

Decentralization and de-medicalization overlap in many but not all respects, with self-management constituting the most decentralized model of care. Decentralization is fundamental to the notion of expanding access to services and the global thrust towards decentralizing abortion care includes expanding access through broad-based availability at numbers of different access points such as pharmacies, (33, 34) primary care services in developing countries and telemedicine service by physicians in developed countries where access is limited (4, 35, 36) as well as task sharing with lower cadres of HCWs. A multipronged approach to decentralizing care may be needed to fully realize the potential of medical abortion in providing care to all who want it. Providing first trimester medical abortion in all primary care facilities and the use of community-based CHWs to inform, screen and refer can go a significant way to expanding access. Remote consultations with health-care providers are possible alternatives, and may have some place in future in South Africa, although telemedicine for abortion care as provided in the US is unlikely due to associated costs. The use of smartphones may be more feasible, and deserves some consideration. The place of mHealth in abortion care and in the South African mHealth strategic plan is further discussed in the section 8.6.

8.5 Autonomy and abortion self-management: meaning, perspectives and implications

In the following section, the notion of autonomy is introduced using a rights perspective in the field of health care generally and in abortion care specifically. Moving to the practical, autonomy as exercised through abortion self-management is considered from the perspectives of women seeking abortion, from providers of abortion care and lastly taking health systems factors into account.

8.5.1 Autonomy in the context of reproductive rights and abortion self-management

Autonomy is generally understood to encompass notions of choice and self-sufficiency, but its meaning may be nuanced according to a particular context. In health-care, patient autonomy is protected through the informed consent process, whereby patients have the right to make their own decisions about their health-care and providers are bound to fully inform and educate patients, but not impose decisions on them. In health-care practice, however, this can present complex problems for health-care providers where concerns about patient safety and welfare compete with freedoms of choice (37).

There has been global progress towards recognizing reproductive autonomy as a human and reproductive right, however a major shortfall in achieving this in both the developed and more so in developing countries, can be ascribed to challenges and barriers to safe abortion care. In the narrower context where this thesis is situated, autonomy for women undergoing abortion implies some choice with respect to abortion method and choice for clinic-based care or self-management. For women self-managing their medical abortion, this autonomy can denote a sense of empowerment, self-sufficiency and control with respect to their decisions and experiences relating to their abortion, as well in relation to their health and general wellbeing (23, 38, 39).

Autonomy must necessarily be grounded in knowledge and understanding (37). As self-managed medical abortion gives women greater autonomy than surgical methods (40), the role of counselling by health care providers must, by extension, be more comprehensive and more time-consuming (22). The importance of empathetic face-to-face counselling on taking medications, what to expect, and managing bleeding and complications has been emphasized (17, 23, 39), and is a key role for nurse clinicians rather than lower cadres in health-care (23). Written materials, although commonly available, are reported to be underutilized (23), however the supportive text messages in Studies 2 and 3 (this thesis) were shown to be effective in strengthening the counselling given at the clinic and highly acceptable to and valued by women.

The nature of this nurse-client/patient interaction in medical abortion care is congruent with Orem's Self-Care Theory of Nursing (this thesis, Chapter 1) which defines and

elaborates the role that nurses play in supporting patients to exercise self-care. As such, the strategies and findings from this research may have relevance for health-care provision in general, beyond medical abortion. A flexible balance between autonomy and dependency in the nurse-client/patient interaction would cater best to the needs of both, as in general, acceptability of self-management is determined according to the balance of perceived benefits versus potential harms in each case (23).

Referring back to the conceptual framework in Fig. 8.1, it is useful to consider where self-management of medical abortion in the above service delivery model differs from other self-managed processes in health-care. Unlike many other health conditions where self-management is encouraged (for example HIV/AIDS, hypertension, TB, and diabetes (29, 41-45)), medical abortion is not a long term condition and self-management does not require sustained adherence or behavior change. In medical abortion, self-management is most feasible when women identify their pregnancy early - within 10 weeks. Following a single clinical assessment, self-management then involves preparation for treatment, compliance with one or two simple treatment regimens, monitoring of progress over two weeks and recognition of complications or the need for additional clinical intervention.

8.5.2 Women's perspectives of self-management

For most women self-management reduces their dependency on providers and can be empowering. For them, the benefits of self-management may include decreased costs, ease of scheduling, decreased transport needs, and the ability to better manage stigma (23, 46). Other benefits include a sense of control, in that arrangements can be made for support and comfort as well as for gathering of materials that will be needed (23, 39, 47, 48). In comparison, negative aspects of clinic settings can include inadequate and inconvenient spaces, with unhygienic public bathrooms that are difficult to access (49).

In contrast, for others, the clinic environment feels safer and provides more privacy and reassurance (23). Women's uncertainties extend to concerns over vomiting medicines, confusion with respect to what analgesics can be used and the potential for these to interfere with the abortion medication (23), while others worry about complications occurring at home with no provider support (49). In the South African informal settlement

context, the home environment may not always be conducive to self-management due overcrowding or lack of privacy from family members, especially for young women. Some of women's concerns that relate to the procedure itself were addressed in the text messages evaluated in Study 2 (this thesis). Where phone privacy is compromised, women can opt out of the message program should they wish to do so. Following the strong positive response by women to the message program (10), a similar program was included in Study 3 (this thesis), which was again very well received, with most women selecting the combination of pregnancy test, checklist and text messages as a self-management package.

8.5.3 Provider's perspectives on self-management

Where providers view medical abortion as a "procedure" rather than a "treatment", they may be reluctant to relinquish supervision and control of the process (50). Thus, while providers' perspectives on self-management in first trimester medical abortion are generally favorable, this is contingent on the process being initiated by trained clinicians (23). The findings in Study 1 (this thesis) echo this perspective among the majority of providers interviewed.

A negative consequence of increased self-management is the moral distancing that self-management allows providers to hold (23). However, the WHO position is unambiguous in this regard - task sharing and self-management of medical abortion should not be a transfer of activities and responsibilities to others due to reluctance of HCPs to provide abortion care (17). Most importantly, where concerns or complications arise for a woman self-managing her own care, HCP availability and intervention should be readily accessible, prompt and effective.

8.5.4 Health services' perspectives on self-management

If well-planned and implemented, task sharing to CHWs can allow for triaging which leads to better use of health resources, including better scheduling, reduced demand and more efficient referral. In addition, quality of care can be enhanced through improving timeliness of processes such as earlier referral and earlier determination of outcome (17). An unintended consequence of self-management could be redistribution to unlicensed providers of mifepristone or misoprostol (23), a risk also identified in programs where misoprostol was distributed by CHWs for postpartum hemorrhage (51). However, these

concerns may be unfounded as they disregard that women seeking abortion do not want to continue with their pregnancies (50). Our findings in Studies 2, 3 and 4 lend credence to the view that this is an unlikely consequence, perhaps less likely than in other health conditions.

8.6 The place of mHealth for abortion care in the mHealth domain

In the following section the place of mHealth for abortion care is discussed within the domain of the mHealth generally and specifically within the South African mHealth strategy. The distinctive characteristics of mHealth for abortion care are highlighted and barriers to mHealth for abortion care are outlined.

Mobile health or mHealth is recognized to have potential for changing the way health-care is delivered (52). Globally and in South Africa, its proponents envision that mHealth will be integrated into the mainstream of health systems, as a mechanism to address health system constraints and to augment the impact of health interventions (53, 54). Recently, global health agencies have encouraged prudent implementation of evidence-based mHealth solutions that have demonstrated functionality and impact in real-world conditions (55). However, the impact of mHealth on health outcomes is hard to show (52). As with Study 2, other randomized controlled trials have identified modest benefits of mHealth for health care delivery (56-58). While there is increasing evidence on efficacy of mHealth for improved treatment adherence and compliance, there are still only small numbers of scaled interventions in LMICs (43).

The mHealth interventions developed for this thesis (known as “m-Assist”) included timed information on symptoms, compliance and appointment reminders and a questionnaire diagnosing a health outcome. Of the six categories for mHealth identified by the 2009 WHO global survey, the m-Assist intervention most closely fits the category of “communication between health services and individuals” (52) which includes deployments aimed at leveraging LMIC health systems to attain the SDGS. Examples are interventions to strengthen maternal and child health, and to reduce the burdens of diseases for conditions such as diabetes and HIV/AIDS. (52). These interventions combine health promotion with appointment and compliance reminders, and thus share similarities with the design and intention with the m-Assist interventions in this thesis.

Other promising mHealth options to strengthen abortion care aim to facilitate health-seeking by individuals, i.e. communication initiated by individuals to health services. Interestingly, the most common mHealth initiatives across all countries have been reported in this category, specifically the use of health call centers (52). The use abortion hotlines and telemedicine for abortion falls into this category, as used by Women on Web and other service providers (36) and the telemedicine service in the US (59), although strictly speaking these not mobile interventions. While there is nothing new about phoning into a health service for information, the immediacy and privacy of mobile phones, the availability of SMS, options for toll-free calls and the quest for information via the internet are relatively recent phenomena and are becoming more broad based as handset ownership increases. It is possible that there will be increased opportunity for mHealth to be used to strengthen and expand safe MA care in South Africa, and to achieve sustainability, this should be integrated formally into the national mHealth strategy.

8.6.1 The South African mHealth strategy

The South African mHealth strategy (60) aims to integrate mHealth into health delivery systems so as to support South Africa's health priorities. In addition, the strategic plan identifies the potential of mHealth to empower individuals and providers and to build infrastructure and capacity for future mHealth requirements. Domains from the strategic plan in which the m-Assist type of intervention could operate include clinical support services and public health and operational management. Compared to the South African government sponsored "MomConnect" text message program that supports ante- and post-natal care, the m-Assist program has the advantage of being of shorter duration and therefore cheaper, less likely to undergo technology failure for any one user, and has been evaluated in an RCT to be effective. There is additional potential for the m-Assist program to be incorporated into abortion care to support task shared activities, which could improve access to safe medical abortion in underserved rural areas, given sufficient infrastructure, phone ownership and privacy.

8.6.2 Barriers to implementation of mHealth

The most common barriers to implementation of mHealth at scale in the public sector involve issues of knowledge, competing priorities in the health sector and cost (52). Policy

makers and administrators require solid evidence on which to base decisions, and there remains a paucity of evidence to verify the impact of mHealth on health outcomes and on health systems across countries of all income levels, although progress is being made (52, 56). Competing health priorities present a challenge to the opportunities for implementing mHealth for abortion care, which is a deeply contested issue in health-care (61). In LMICs, most public and private sponsored mHealth programs focus on maternal, newborn, and child health (MNCH), with the primary target beneficiaries are pregnant women and mothers (62). Nonetheless, there are some leading voices in mHealth advocating for a greater focus on gender in women-centered mHealth initiatives, with the specific aim of empowering women (62, 63). It may be that incoprorating abortion mHealth into family planning mHealth interventions is a feasible approach.

A final criterion determining whether mHealth programs can be implemented is cost-effectiveness. This applies equally to other self-management strategies like the LSUPT. Relatives costs need to be evaluated comparing scaled up m-Assist type of interventions to provider time spent on additional calls and visits, as well as women's costs related to these activities. In mHealth, it is recognized that there is a tension between the two stakeholder groups – the health sector goal of universal access to care, and the profit motive of the private telecom businesses. Possible financing models include cross financing where paying subscribers subsidize non-payers. Telecom companies are unlikely to offer long-term sponsorship for mHealth to support abortion care, however, for a short period ending in 2015, a text message program based on the m-Assist program was subsidized by a local telecom provider and offered by IPAS in South Africa (http://catapult.org/changing-womens-lives-just-few-text-messages/ Accessed 04 March 2016). While beneficial in the short term, the lack of sustainability of donor-sponsored programs is a problem for the long term goals of an intervention aimed at the public health sector. Alternative mHealth solutions to achieve similar or even more broadly reaching benefits in abortion including sexual and reproductive health care may be the use of toll-free hotlines offering advice on numbers of reproductive issues. Alternatively, similar but shortened text message programs as used in other settings (64) (Gerdts, C et al. Manuscript in preparation, 20/08/2106) may be more feasible in terms of cost for implementation in the South African public health sector.

8.7 Potential new approaches for strengthening medical abortion

This section describes recent progress in protocols for MA and explores some further strategies to improve access. The section ends by proposing a model of service delivery for MA at primary care level which outlines processes, role payers and supporting mechanisms.

The early service delivery models for medical abortion with mifepristone in developed countries in the early 1990s were highly medicalized, involving multiple clinic visits, with provision limited to doctors, and used high dosages of mifepristone with an associated high cost (25). This was directly contrary to a public health approach, despite the suitability of the method for primary care settings. In addition, these barriers imposed unnecessary delays, limiting the opportunity for safe, decentralized care which is best suited to early procedures (65).

8.7.1 Medical abortion protocols in the Western Cape public sector

There has been progress in the development of protocols in the South African public sector since the first introduction of medical abortion with mifepristone and misoprostol. The protocol for medical abortion developed by the Western Cape DOH in 2010 was evidence based in that (a) the 200mg mifepristone dosage was used, (b) the gestational limit was increased to 63 days (from 56 days) and (c) home use of misoprostol was offered. As shown in Figure 1.1 (Chapter 1), the 2010 Western Cape protocol required an ultrasound exam to determine gestational age eligibility as well as an in-clinic follow-up visit for assessment and contraceptive provision. In addition, the guideline did not consider that eligible women could be offered a choice of method, if available, but did offer the choice for home or clinic use of misoprostol, although this option has not been implemented to any extent in practice. Research in this thesis and elsewhere has explored the possibilities of a simpler more de-medicalized models for abortion provision for LMIC and HMIC settings (13, 33, 66).

The Western Cape updated protocol was released in March 2016 after completion of the studies included in this thesis (67). Compared to the 2010 version, it emphasizes that women seeking abortion should access health services at primary level for pregnancy testing and clinical evaluation, as well as referral to a designated abortion facility. These amendments allow for clinical examination combined with last menstrual period dating to

establish gestational eligibility and for in-clinic follow-up to take place at clinics other than the abortion facility. The protocol still involves two to three clinic visits, with allowance for the first and final visit to be at local primary care facilities. However, a choice of medical or surgical methods is not offered to women who are eligible for both.

An important additional amendment is that medical abortion may be offered to women with gestations between 64 and 84 days, providing the procedure is conducted by a medical doctor and on an in-facility basis for the administration of drugs. The guideline does not specify whether mifepristone may be self-administered at home, but follows the WHO 2014 guideline drug protocol for misoprostol (67).

8.7.2 Next steps: extending out of clinic MA up to 70 days, or beyond

The evidence that abortion can be safely self-managed out of clinic up to 70 days GA with mifepristone and misoprostol is compelling, and applies in diverse settings (68-70). With the aim of further expanding access, the safety of extending the GA to 77 days is currently being explored (71). The WHO has not recommended self-management for MA up to 70 days GA, as no evidence was available at the time of the guideline (17). However, the updated labelling for mifepristone up to 70 days GA by the US FDA is a spur to action for similar provision in South Africa and other developing countries.

In the US, extending the GA cut-off to 70 from 49 days, results in twice as many women being eligible (72). In South Africa, Western Cape public sector service data (Unpublished data), and data from Study 1, both show that approximately 8% more women presenting for abortion care would be eligible for MA if the GA limit was extended to 70 days, although a high proportion of women still present for care after the first trimester. In the US and elsewhere in Europe women in the first trimester are presenting earlier at facilities than in the past, which holds promise for similar trends globally if structural delays can be reduced (72, 73).

8.7.3 Off-site administration of mifepristone

Other novel ways of providing medical abortion that expand access and provision outside of clinic settings have been implemented where access is limited. These include the elimination of the initial clinic visit for selected women using LMP, or where feasible, the

use of laboratory-confirmed serum hCG for GA estimation (33). When combined with off-site provision of mifepristone, which can be safely executed by a trained provider via a telemedicine service, the need for a clinic visit is avoided entirely (4, 36, 74). The laboratory/telemedicine approach, although of interest, involved complex technology and is unlikely to gain traction in the near future for settings like South Africa. There is a strong presence of online un-licensed providers of MA in South Africa, which women commonly turn to if denied care in licensed facilities, but little is known about other reasons women access these services in preference to consulting licensed providers (75).

However, off-site self-administration mifepristone has immediate relevance in the South African public sector context. This offers women greater flexibility and autonomy, has been shown to be safe and acceptable in research from various settings, and has been incorporated in guidelines in some countries, examples being Australia, Armenia, and Azerbaijan and Nepal (34, 50, 76, 77). The benefits of off-site self-administration of mifepristone for women include flexibility to best manage their daily commitments and time to arrange for privacy or support (50). Opinion of local providers in the public sector who participated in this thesis research is that on-site observed administration of mifepristone in the first trimester ensures greater safety, preventing any delays in taking the medication, which could result in additional risk of more bleeding or a failed procedure. In support of off-site mifepristone for first trimester MA, Study 4 (this thesis) documented safe off-site self-administration of mifepristone prior to admission in second trimester medical abortion. However, it must be noted that for second trimester MA, the same safety concerns do not arise as misoprostol is administered in-facility and the abortion is monitored until completion.

8.7.4 A possible role for pharmacists

In various settings, combination packs of mifepristone and misoprostol are dispensed from pharmacies, which allows for off-site self-administration of both medications. In developed country settings where abortion is legal and unrestricted, this is closely regulated with risk management plans in place (34), and this option has expanded, but not replaced abortion clinic service delivery. Dispensing from pharmacies has been recommended for inclusion where access is limited, and has also been implemented in some developing countries (34,

78). However, in some settings where pharmacists and pharmacy workers are the first line providers, it has been shown that accurate information and quality care is not consistent (78, 79).

For the South African public sector, this service model of assessment, counselling and prescription by health care providers, dispensing by pharmacists and self-administered off-site of medications has the potential to circumvent the requirement to attend a designated abortion service in a health-care center, and could substantially expand access to MA to many broad based service points. This could also be an advantage for women not wanting to be seen to be seeking care from a designated abortion facility due to the pervasive stigma of abortion. While this model of service delivery could expand access, if implemented it should augment rather than replace the designated facility model and women should be offered the option of self-management (with or without mHealth support) or provider-assisted care.

In the South African private sector, prescription of both mifepristone and misoprostol by a medical practitioner, dispensing by pharmacists and off-site self-administration is common practice. However, some pharmacies hinder women's access to mifepristone by not stocking the drug - which has occurred in some public sector hospital pharmacies as well (personal communication, Mifepristone distributer, South Africa; June 2016). To overcome this, current work-around solutions involve establishing networks of HCPS and pharmacists willing to provide these services, and expanding these networks at every opportunity. Key government stakeholders in charge of reproductive health programs are working to stop this practice in the public sector (Stakeholder meeting, 23August 2016). Other negative aspects of pharmacy provision in the private sector are over-pricing, where pharmacies will only dispense 3x200mg mifepristone tablets, and refuse to dispense beyond 56 days GA in line with the original, but outdated MCC approval (personal communication, Mifepristone distributer, South Africa; June 2016).

8.7.5 Self-assessment with the LSUPT

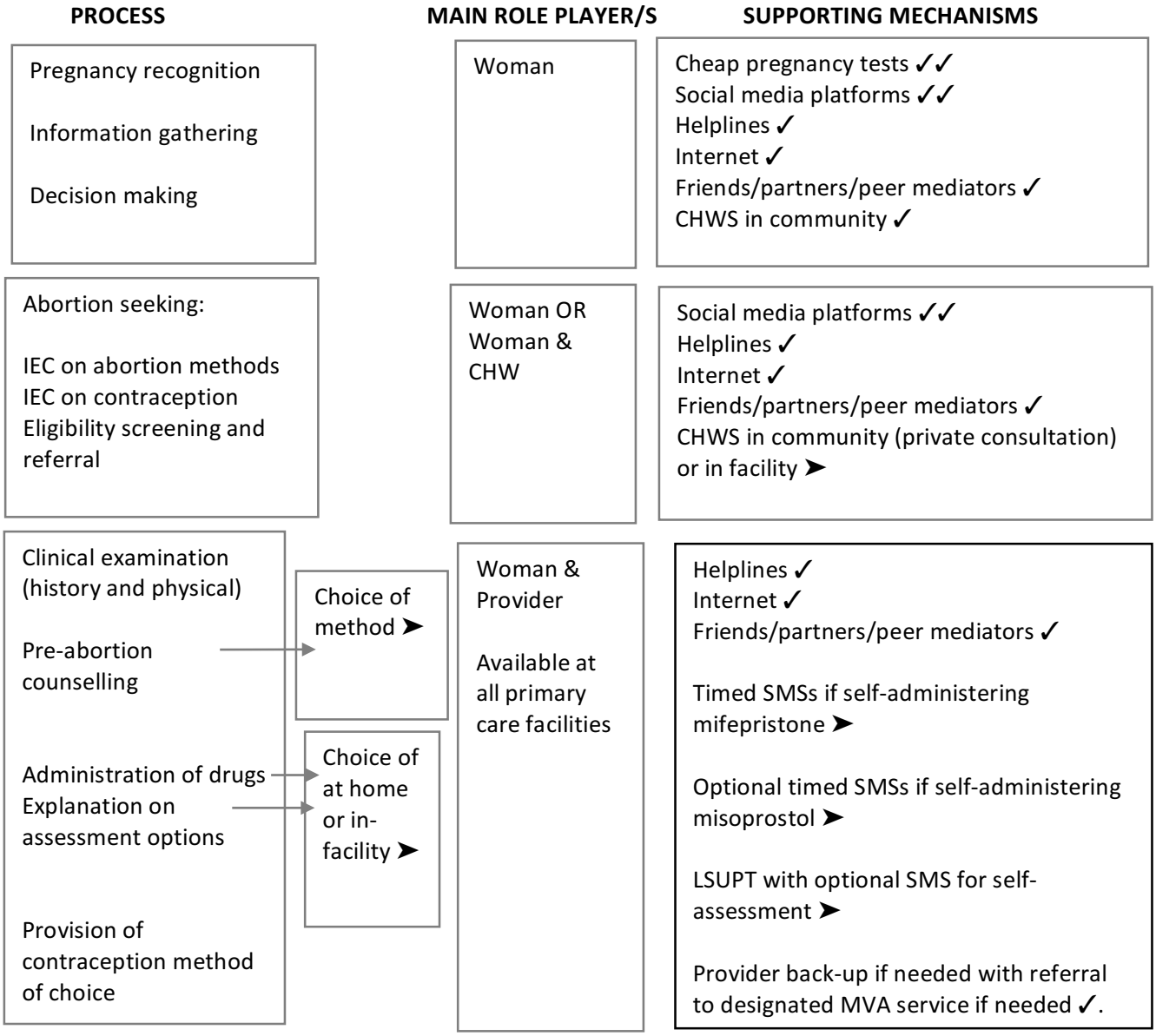
Self-assessment of abortion outcome with the LSUPT has been incorporated into service delivery in some developed countries including the UK and in parts of Sweden (14),

(Gemzell-Danielsson, K. Oral presentation at ESCRH, 07 May 2016). Developing countries where research has documented safe and acceptable safe-assessment for first trimester medical abortion include Vietnam, Moldova, Uzbekistan and most recently, India and Tunisia (11, 12, 15, 16, 80). From the research in this thesis, the LSUPT looks promising for the South African setting, however, an analysis of costs is likely to be necessary for the implementation. Economy of scale is needed to reduce the price of the test; to achieve this the LSUPT needs to be offered across all sectors. Women attending public facilities are unlikely to be willing to pay for such a test as reproductive health care is free in the public sector. A study demonstrating the number of in-clinic follow-ups (evaluated as provider time) that could be avoided though self-assessment using the LSUPT may serve this purpose. As both mifepristone and the LSUPT is supplied by Exelgyn, combining these into a single care package may be a mechanism whereby a feasible price could be negotiated.

8.7.6 Implications and recommendations for service delivery of first trimester medical abortion care at primary care level

A model of service delivery for MA at primary care level is proposed (Figure 8.2) which outlines processes, role payers and supporting mechanisms. The figure identifies characteristics of service delivery that improve access and are currently available, mechanisms that are available in a narrow sector of mostly in urban locations, and mechanism or strategies that could be made available and would strengthen care if implemented in the future.

Figure 8.2 Implications and recommendations for first trimester MA service delivery



Characteristics of service delivery model	**Key to symbols and acronyms**
Single interaction with clinical nurse practitioner	✓✓ Currently available (dependent on geography, infrastructure, personal circumstances)
Single clinic visit (Two clinic visits, in facility day care for misoprostol administration for women with GA>70 days)	✓ Somewhat or probably available in urban centers
Autonomy with respect to method choice, self-administration of drugs, and self-assessment	➤ Possibly available in future
Supportive mechanisms to strengthen safety acceptability	IEC: Information, education & communication

In summary, abortion within a legal context should not be difficult to access. In the South African public sector MA up to 70 days GA should be provided at all primary care facilities that offer family planning services. For MA later in the first trimester designated facilities with space for daycare and medical practitioner back up on hand are suitable, particularly if there are no MVA services in the area. MA in the second trimester using the mifepristone-misoprostol regimen needs to be introduced into district and tertiary level public sector hospitals across the country as D&E providers are scarce and likely to remain so.

Interventions to strengthen access to services are needed to address the multiple large and small barriers women encounter. The use of the interventions developed and evaluated in this thesis, coupled with broader-based availability should go a significant way towards normalizing MA, such that the decision by women to end an unwanted pregnancy is not further fraught with challenges to access care that should, by right, be easily available.

8.8 Recommendations for further research

This thesis has documented some safe, effective and acceptable strategies to strengthen task sharing the individual subtasks involved in first trimester medical abortion. However, other than Study 4, these studies were performed in a research setting, and no one study investigated task sharing or self-managing the overall process of medical abortion.

For policy makers to implement any one or all of these approaches, further research is recommended to answer the following questions:

1. What is the impact of each of these strategies on the health system and what are the experiences of providers, CHWs and women in rural and remote settings?
2. What are the cost implications of self-assessment using a suitable pregnancy test?
3. What are the safety implications for self-management taking all medical abortion subtasks together, or in various combinations?
4. How effective are risk management plans, such as mhealth or help-lines, for self-managed abortion care?

For medical abortion care after 70 days, these questions need addressing:

5. In areas where there is no MVA service in South Africa, what is the feasibility of providing medical abortion with in-facility day-care for pregnancies up to 84 days?
6. In underserved areas in South Africa, what are women's preferences with respect to abortion method for those seeking abortion with pregnancies in the late first trimester: medical abortion with in-facility care, or travel to an MVA facility if not provided at that facility?

For medical abortion care in the second trimester, evidence is needed on the following:

7. What are indications for surgical evacuation of placental tissue following medical abortion with mifepristone and misoprostol in the South African public sector hospital settings?
8. What are the costs of second trimester medical abortion with mifepristone-misoprostol compared to the misoprostol-only regimen?

8.9 Conclusions

The introduction of medical abortion was expected to rapidly expand access to abortion care, however earlier service delivery models for medical abortion using mifepristone were highly medicalized, with strict limitations relating to who could receive the method as well as when, how and where the service could be provided. As a result, the potential for broad-based and decentralized provision was not immediately realized.

This thesis demonstrates novel ways in which task sharing and self-management in abortion care could be introduced into the public sector primary care service environment in South Africa. In addition, this work describes an improved model for second trimester medical abortion care, which is much-needed in South Africa, where substantial numbers of women seeking care are in the second trimester of pregnancy. The findings have relevance for other similar settings where there are barriers to access, provider shortages and uneven provision, and where the potential for medical abortion to expand has been frustrated by overly medicalized service delivery requirements.

This thesis also demonstrates that mHealth is a modality well-suited to support self-managed subtasks in abortion care. Results suggest this modality can be used in innovative ways to achieve further gains in strengthening provision of care, especially in remote areas, given adequate telecommunication infrastructure.

All the strategies described in this thesis require extensive engagement with policy makers and health care workers at facility level if implementation is to be taken forwards, however the evidence presented here, substantiated by that from many other settings, could contribute significantly to the expansion of safe, accessible, effective and acceptable abortion care.

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Appendix 1 . Study 1 (Ethics)

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Faculty of Health Sciences Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: sumayah.ariefdien@uct.ac.za

23 November 2011

HREC REF: 483/2011

Dr J Harries
Women's Health Research Unit
Public Health & Family Medicine
Falmouth Building

Dear Dr Harries

PROJECT TITLE: HOW WELL DO COMMUNITY HEALTH WORKERS ASSESS ELIGIBILITY AND FOLLOW-UP CARE FOR EARLY MEDICAL ABORTION: A MULTI-COUNTRY VALIDATION OF ASSESSMENT TOOLS.

Thank you for addressing the concerns raised by the ethics committee.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted for one year till the 28 November 2012.

Please submit a progress form, using the standardised Annual Report Form (FHS016), if the study continues beyond the approval period. Please submit a Standard Closure form (FHS010)if the study is completed within the approval period.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

Signed

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

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Appendix 2 Study 1 (Study Instruments)

World Health Organization

A65779 - Assessment of eligibility and follow-up care for early medical abortion

ASSESSMENT OF ELIGIBILITY

ASE
page 1/2
10 May 2012

Center number | Screening number | Subject Number

1. Facility Name:
1 = MS Durban
2 = MS Isipingo
3 = Cato Manor
4 = MS Umlazi
5 = Mosaic

2. Assessor:
1 = CHW
2 = Clinician

a) Assessor ID:

3. Date of assesment: Day | Month | Year

URINE PREGNANCY TEST

4. Result of urine pregnancy test: 1 2
1 = Negative
2 = Positive

If Negative the woman is not eligible for medical abortion.

LAST MENSTRUAL PERIOD

5. Does the woman know last date of menstrual period? 1 2
1 = No
2 = Yes

If No, the woman should see a health provider for abortion service.

a) What was the date of her last menstrual period? Day | Month | Year
(If the woman does not remember exact date, ask for an approximate date)

b) Is that exact date or approximate date of her last menstrual period?
1 = Exact date
2 = Approximate date

USE THE PREGNANCY WHEEL

6. Where is the arrow pointing? 1 2
1 = Blue area
2 = Red area

If the arrow is in the red area, she is not eligible for medical abortion. She should see a health provider for abortion services.

If the arrow is in the blue area, then record duration of pregnancy:

a) Weeks | b) Days

HEALTH STATUS CHECKLIST

Ask the woman the following questions:
1 = No
2 = Not sure
3 = Yes

	1	2	3
7. Did you have unusual bleeding during your last period?			
8. Do you have bleeding problems? *(Very heavy bleeding after childbirth or miscarriage, cuts that don't stop bleeding, or frequent severe nosebleeds)*			
9. Do you have a history of inherited porphyria?			
10. Have you ever had a pregnancy in your tubes, i.e. an ectopic pregnancy?			
11. Have you had your tubes tied (female sterilization)?			
12. Do you have any serious illnesses or medical conditions?			
13. Are you taking any prescribed medicines?			

World Health Organization

A65779 - Assessment of eligibility and follow-up care for early medical abortion

ASSESSMENT OF ELIGIBILITY

ASE
page 2/2
10 May 2012

Center number ☐☐☐ Screening number ☐☐☐ Subject Number ☐☐

	1	2	3
14. Do you have a loop /IUC /IUCD now? *(Copper T, Mirena)*	☐	☐	☐
15. Do you have abdominal pain or bleeding today?	☐	☐	☐
16. Have you ever had an allergic reaction to medical abortion pills?	☐	☐	☐

ELIGIBILITY ASSESSMENT

If there is no tick in the shaded box, the woman is eligible for medical abortion today.

If there is at least one tick in the shaded box, the woman might not be eligible for medical abortion. Ensure the woman sees health care provider.

17. Do you think this woman is eligible for medical abortion today? ☐

1 = No
2 = Yes

World Health Organization

A65779 - Assessment of eligibility and follow-up care for early medical abortion

CLINICAL EXAMINATION - ELIGIBILITY

EXE

10 May 2012

Center number ☐☐☐☐ Screening number ☐☐☐☐ Subject Number ☐☐

1. Facility Name: ☐
   1 = MS Durban
   2 = MS Isipingo
   3 = Cato Manor
   4 = MS Umlazi
   5 = Mosaic

2. Clinician ID: ☐☐

3. Date of examination: Day ☐☐ Month ☐☐ Year ☐☐☐☐

CURRENT PREGNANCY

4. Has the woman had any of the following signs of pregnancy during the last seven days?
   1 = No
   2 = Yes

   a. Nausea: ☐
   b. Vomiting: ☐
   c. Abdominal pain: ☐
   d. Bleeding: ☐
   e. Other signs of pregnancy: ☐
      i) If Oher, please specify: _____

5. Is any clinical condition not well controlled? ☐
   1 = No
   2 = Yes
   a) If Yes, please specify: _____

CLINICAL EXAMINATION

6. Abdominal examination: ☐
   1 = Not done
   2 = Normal
   3 = Tender
   4 = Other abnormality
   a) If Other Abnormality, please specify: _____

7. Abnormal vaginal discharge: ☐
   1 = No
   2 = Yes
   a) If Yes, please specify: _____

8. Is the IUCD still in situ? ☐
   1 = No
   2 = Yes

9. Does the woman have a PID? ☐
   1 = No
   2 = Yes
   a) If Yes, specify treatment: _____

10. Is an ectopic pregnancy suspected? ☐
    1 = No
    2 = Yes
    a) If Yes, is ectopic confirmed by ultrasound? ☐
       1 = No
       2 = Yes

11. Gestational age assessed by clinical examination /bimanual: (Weeks) ☐☐

World Health Organization

A65779 - Assessment of eligibility and follow-up care for early medical abortion

CLINICAL EXAMINATION - ELIGIBILITY

EXE

10 May 2012

Center number ☐☐☐☐ Screening number ☐☐☐☐ Subject Number ☐☐

12. Gestational age assessed by ultrasound:
    a) Weeks: ☐☐ b) Days: ☐
    c. Not done: ☐

13. Is the woman eligible for a Medical TOP? ☐
    1 = No
    2 = Yes
    a) If No, why not? _____

Semi-structured in-depth interview guide for CHWs

Introduction:

Thank you for agreeing to participate in the study and for taking part in this interview. As you know, we are doing research on the potential role of community health workers in the provision of medical abortion. We are therefore interested in knowing whether CHWs can contribute to safe abortion services by identifying women who are eligible for medical abortion and identifying those who have an unsuccessful abortion. The information that you provide may help to make abortion safer and more accessible for other women. I would like to ask you some questions about your thoughts and experiences of working as a CHW and particularly in relation to your participation in this study. Please feel free to speak as openly as possible, there are no right or wrong answers. If you do not wish to answer any of the questions you do not need to so. We can stop the interview at any time.

1. I would like to start by asking you a little more about your past work as a CHW and what your current role at the clinic entails.

Probes:

- How long have you been a CHW?
- What type of services have you provided in the past?
- What type of services are you currently offering at this clinic?
- What type of training have you undergone?

2. With regards to this study, do you think the training you received to assess women for medical abortions was adequate?

Probes:

- How would you improve the training?
- What additional training, if any would you liked to have received?
- Practical training – experiences of using the pregnancy wheel and the questionnaires
- Pre and post test

3. Having had training, how do you feel about your skills in assessing women and referring them for a medical abortion?

Probes:

- Which tasks did you find most difficult when providing medical abortion assessments and why? (pregnancy test, questionnaires, pregnancy wheel)
- Which tasks did you find the least difficult and why?

4. Difficulties associated with implementing the study(for MSI) CHWS only

Some difficulties were encountered at the beginning of the study at the MSI sites in the Durban area – could you provide some background as to why you think this occurred?

5. Based on your experience of this study would you have any concerns about referring women for a medical abortion? If yes, could you please explain? If no, could you explain?

During the study the eligibility and follow up screening was conducted at MSI /Mosaic. Based on your experiences in this study, how would you feel about providing guidance on medical abortion during a home visit or elsewhere in the community?

Probes:

- Which other setting(s) do you think CHWs could be placed to provide such guidance?
- Would it be difficult to visit women in their homes our outside of the clinic – if so why do you think it might be difficult?

6. With regards to the study. How do you think women felt about being assessed by a CHW first and then by a health care provider?
   Probes:
   - Did the women appear comfortable about being assessed by a CHW?
   - Did the women raise any concerns about being assessed by a CHW?

7. What are your views with regards to CHWs role in assisting with medical abortion services? Do you think there are other types of assistance that CHWs could provide? If so, could you describe what kinds of services could CHWs provide.

8. Could you discuss what you have learned from your experience of being involved in this study?

9. Do you have any other comments, suggestions or questions you would like to ask?

We have now come to the end of the interview. Thank you very much for your time and participation.

Semi-structured in-depth interview guide for Providers

Introduction:

Thank you for agreeing to participate in our study, and for agreeing to participate in this interview. As you know, we are doing research on the potential role of community health workers in the provision of medical abortion. We are therefore interested in knowing whether CHWs can contribute to safe abortion services by identifying women who are eligible for medical abortion and identifying those who have an unsuccessful abortion. I would like to ask you some questions about your experience and opinion with the evaluation and the acceptability on the role of community health workers, particularly in relation to medical abortion services. Please feel free to speak as openly and as honestly as possible, there are no right or wrong answers. If you do not wish to answer any of the questions, we can stop the interview at any time.

1. I would like to start by asking you to describe your past work as a health care provider and your current role(s) at the clinic.

Probes:

- How long have you been a registered nurse?
- What type(s) of settings have you worked in previously (e.g. government facility, NGO etc.)?
- How long have you been involved in TOP services?
- What abortion training have you received and when?
- How long have you been employed at this clinic?

2. In your professional capacity, have you worked with CHWs in the past? If yes, please describe your experiences of working with CHWs.

3. What are your opinions regarding the level of training received by the CHWs for this study to assess women for medical abortions?

Probes:

- Do you have any suggestions for other areas of training required for CHWs as it relates to medical abortion?
- What additional training, if any, do you think should have been included?

4. Based on this study, how would you feel about allowing CHWs to refer women for medical abortion?

Probes:

- Concerns about CHWs' ability to perform these functions
- Medical abortion services should only be provided by health care providers
- CHW involvement could increase women's ability to reach care within the earlier especially for medical abortion which needs to be before 9 weeks.

5. Based on this study, how would you feel about allowing CHWs to refer women for a follow up after a medical abortion?

Probes:

- Concerns about CHWs' ability to perform the required functions
- Medical abortion services should only be by health care providers
- CHW involvement could increase women's ability to reach care within the specified timeframe(i.e. before 9 weeks)

6. Based on your experience in this study, how do you feel about CHWs providing guidance on medical abortion in the community setting?

Probes:

- Which setting(s) do you think CHWs could be placed to provide such guidance?

7. Please describe how you think the clients felt about being assessed by a CHW for MA services.

Probes:

- Did the women raise any concerns about being assessed by a CHW?
- If so what were these concerns?

What are your opinions regarding CHWs assessing women for MA services? What do you see as the advantages and disadvantages?

8. What are your views about this clinic incorporating the strategy of CHWs providing medical abortion referral and follow-up services? What might be the advantages and disadvantages?

9. Could you describe your overall experiences of being involved in this study?

10. Do you have any other comments, suggestions or questions you would like to ask?

We have now come to the end of the interview. Thank you very much for your time and participation.

Appendix 3 Study 2 (Ethics)

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6626 • Facsimile [021] 406 6411
e-mail: shuretta.thomas@uct.ac.za

14 April 2011

HREC REF: 477/2010

Dr D Constant
Women's Health Research Unit
Public Health & Family Medicine

Dear Dr Constant

PROTOCOL NUMBER: A65721
PROJECT TITLE: THE USE OF A PACKAGE OF INFORMATION, SELF ASSESSMENT, AND SUPPORT AS AN ALTERNATIVE TO FOLLOW-UP VISITS AFTER MEDICAL ABORTION AND TO STRENGTHEN FP MESSAGES.

Thank you for your letter to the Faculty of Health Sciences Human Research Ethics Committee dated 11th April 2011.

The HREC **noted and approved** the following documentation for the above-mentioned study:

1. Protocol version 5.0, dated 20 December 2010
2. Appendix A: Informed Consent English, Afrikaans & Xhosa version 4.0 dated 11 April 2011

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC. REF in all your correspondence.

Yours sincerely

Signed

PROFESSOR M BLOCKMAN
pp CHAIRPERSON, HSF HUMAN ETHICS

S Thomas

Appendix 4 Study 2 (Study Instruments)

Baseline interview

A. BACKGROUND QUESTIONS I'll start by asking some questions about your background.		
Q#	Question	Coding Category
A1	**How old are you?** **[*IF UNDER 18 YEARS END INTERVIEW*]**	___ ___ Age in years -99 = Refused -66 = Missing
A2	**Which area do you live in?**	_____ -99 = Refused -66 = Missing
A3	**Which population group do you belong to?** ***READ ALL OPTIONS***	1 = African 2 = Indian 3 = Coloured 4 = White 5 = Other [*SPECIFY*]: _____ -99 = Refused -66 = Missing
A4	**What is your home language?**	1 = *isi*Xhosa 2 = Afrikaans 3 = English 4 = Other [*SPECIFY:* _____ -99 = Refused -66 = Missing
A5	**What is the highest level of education that you have completed?** ***[IF P RESPONDS IN "STANDARD", CONVERT TO GRADE = STANDARD + 2]***	Grade: ___ ___ Post-secondary of a year or more: 13 = College (e.g. secretarial or technical) 14 = University -99 = Refused -66 = Missing
A6	**Are you married or in a stable long-term relationship (for a year or more) with the partner who was involved in this pregnancy?**	0 = No 1 = Yes -99 = Refused -66 = Missing

A7a **A7b**	**Are you now working or studying full-time, working part-time, doing casual work from time to time, self-employed, or not working at all?** ***FOR OPTIONS 1,2,3*** **What work do you do**	1 = Working or studying full-time - Specify (e.g. scholar/student/ clerk/professional): _____ 2 = Working part-time - Specify _____ 3 = Casual worker - Specify _____ 4 = Self-employed in own business 5 = Not working at all **-99 = Refused** -66 = Missing
A8	**What kind of home do you live in?** ***READ CHOICES***	1 = Own home (formal brick house or flat) 2 = Rented house or flat 3 = Live/rent room in someone else's home 4= Shack/informal dwelling 5 = Other (*please specify*): _____ -99 = Refused -66 = Missing
A9	**Do you have electricity in your home?**	0 = No 1 = Yes -99 = Refused -66 = Missing
A10	**Do you have an inside toilet in your home?**	0 = No 1 = Yes -99 = Refused -66 = Missing
A11	**Do you have running water inside your home?**	0 = No 1 = Yes -99 = Refused -66 = Missing

B. REPRODUCTIVE HISTORY **Now I will ask you some questions about your pregnancies**		
Q#	Question	Coding category
B1	**How many times have you been pregnant in your lifetime including this pregnancy now?**	___ ___ Number of pregnancies -88 = Don't know -99 = Refused -66 = Missing

B2	**How many of these pregnancies resulted in:** ***READ ALL*** **Normal vaginal birth** **Cesarean section** **Termination of pregnancy [INCLUDES TODAY'S TOP]** **Miscarriage (spontaneous abortion)** **Ectopic (tubal) pregnancy**	Number Refused Missing a. ___ ___ -99 -66 b. ___ ___ -99 -66 c. ___ ___ -99 -66 d. ___ ___ -99 -66 e. ___ ___ -99 -66
B3	***[DO NOT ASK THIS, EXTRACT FROM CLIENT FOLDER]*** **Gestational age at this TOP**	___ W ___ D GA weeks days

C. THIS MEDICAL ABORTION **Now I am going to ask you about support that you may have, and about your feelings and your expectations around this abortion**		
Q#	Question	Coding category
C1	**Did you yourself want to have this abortion** *READ OPTIONS*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing
C2	**Did other people put pressure on you to have this abortion** *READ OPTIONS IF NEEDED*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing
C3	**Were any other people against you having this abortion** *READ OPTIONS IF NEEDED*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing
C4	**How difficult was it to decide whether or not to have this abortion** (Adler, 1975) *READ OPTIONS IF NEEDED*	1 = No Not at all difficult 2 = No, Not really difficult 3 = Yes, Somewhat difficult 4 = Yes, Very difficult -88 = Don't know

		-99 = Refused -66 = Missing
C5	**Does anyone else at home know about your abortion**	0 = No 1 = Yes -88 = Don't know -99 = Refused -66 = Missing
C6	**Is there anyone who will be at home to support you after you have taken the next tablets for this abortion**	0 = No 1 = Yes -88 = Don't know -99 = Refused -66 = Missing
C7	**On this scale 0 is no bleeding and 10 is very heavy bleeding** **How much bleeding do you expect to experience when the pills that you take by yourself start to work** **Remember if you bleed more than 6 maxi pads in 2 hours you should call the clinic**	Number Don't know Refused Missing ___ ___ -88 -99 -66
C8	**On this scale 0 is no pain and 10 is worst possible pain** **How much pain are you expecting to experience when the pills that you take by yourself start to work** **Remember to take pain tablets if you need them**	Number Don't know Refused Missing ___ ___ -88 -99 -66

D. FEELINGS

Now I will read a list of FEELINGS and ask you how strongly you experienced these in relation to this abortion:

In the last 2 weeks up to this moment now: Did you at any time experience…

READ the Question and all the OPTIONS

Q#	Question	Coding category					
D1	**Shame**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D2	**Embarrassment**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D3	**Regret**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D4	**Guilt**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N

D5	**Anxiety**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D6	**Relief**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D7	**Fear of Disapproval**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D8	**Anger**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D9	**Depression**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D10	**Happiness**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D11	**Doubt**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N
D12	**Disappointment in Self**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	N

(MODERATELY = SOME, NOT A LOT AND NOT A LITTLE)

E. FAMILY PLANNING Now I will read a list of Family Planning methods. **I would like to check with you if you have used any of these methods in the LAST 12 MONTHS.**					
Q#	Question	Coding category			
E1	In the past 12 months have you used *[READ LIST]*		No	Yes	Missing
		a. Oral contraceptive pills	0	1	-66
		b. 2 or 3 Monthly Injections (Depo/ Nur Isterate)	0	1	-66
		c. Emergency contraception	0	1	-66
		d. Male condom	0	1	-66
		e. Female Condom	0	1	-66
		f. Intra-uterine device (IUD / Copper T / LOOP)	0	1	-66
		g. Any other method *SPECIFY* _____	0	1	-66
E2	Did you receive information from the clinic staff today about [*READ LIST]*		No	Yes	Missing
		a. Oral contraceptive pills	0	1	-66
		b. 2 or 3 Monthly Injections (Depo/ Nur Isterate)	0	1	-66
		c. Emergency contraception	0	1	-66
		d. Male condom	0	1	-66
		e. Female Condom	0	1	-66
		f. Intra-uterine device			

		(IUD /Copper T / LOOP)	0 1 -66
		g. Any other method	0 1 -66
		SPECIFY _____	

F. CELLPHONE-RELATED QUESTIONS This study involves using cellphones in medical abortion so we'd like to know more about how you currently use your phone.		
Q#	Question	Coding category
F1	Are you on prepaid or contract?	1 = Prepaid or contract with TOP UP 2 = Contract (cannot get prepaid airtime) -99 = Refused -66 = Missing
F2	How much airtime do you usually have? *LISTEN TO CLIENT AND CIRCLE BEST OPTION* *PROBE IF NECCESSARY*	1 = I always have airtime 2 = Sometimes I have airtime and sometimes I don't 3 = Just enough to MXit or Facebook 4 = Other OTHER Specify _____ -99 = Refused -66 = Missing
F3	How likely is it that people would see SMSs that you get? *READ CHOICES*	1 = Very likely 2 = Might happen 3 = Not likely 4 = Never -99 = Refused -66 = Missing
F4	**Does anyone else ever use your phone?** *READ CHOICES*	1 = Very often 2 = Sometimes 3 = Almost never 4 = Never -99 = Refused -66 = Missing
F5	**Do you use MXit?**	1 = Yes 2 = No -99 = Refused -66 = Missing
F6	**(If client uses MXit) I want to ask how you use MXit. I'll read some different ways of using MXit and you can say if you use MXit in this way.** **READ ALL**	No Yes Missing a. Chat to friends/contacts 0 1 -66 b. Read things 0 1 -66 c. Answer questionnaires 0 1 -66 -99 = Refused -66 = Missing

These next questions ask about anxiety or depression. For each question, point to the answer that best describes how you felt <u>in the past 2 weeks including today</u>

Q#	Question	Answer	Score
1	**I feel tense or "wound up":**	Most of the time	3
		A lot of the time	2
		Occasionally	1
		Not at all	0
2	**I still enjoy the things I used to enjoy:**	Definitely as much	0
		Not quite so much	1
		Only a little	2
		Hardly at all	3
3	**I get a sort of frightened feeling as if something awful is about to happen:**		
		Very definitely and quite badly	3
		Yes, but not too badly	2
		A little, but it doesn't worry me	1
		Not at all	0
4	**I can laugh and see the funny side of things:**		
		As much as I always could	0
		Not quite so much now	1
		Definitely not so much now	2
		Not at all	3
5	**Worrying thoughts go through my mind:**		
		A great deal of the time	3
		A lot of the time	2
		From time to time, but not too often	1
		Only occasionally	0
6	**I feel cheerful:**		
		Not at all	3
		Not often	2
		Sometimes	1
		Most of the time	0
7	**I can sit at ease and feel relaxed:**		
		Definitely	0
		Usually	1
		Not Often	2
		Not at all	3

Q#	**Question**	Answer	Score
8	**I feel as if I am slowed down:**		
		Nearly all the time	3
		Very often	2
		Sometimes	1
		Not at all	0
9	**I get a sort of frightened feeling like "butterflies" in the stomach:**		
		Not at all	0
		Occasionally	1
		Quite Often	2
		Very Often	3
10	**I have lost interest in my appearance:**		
		Definitely	3
		I don't take as much care as I should	2
		I may not take as much care as I should	1
		I take just as much care as ever	0
11	**I feel restless as if I have to be on the move:**		
		Very much indeed	3
		Quite a lot	2
		Not very much	1
		Not at all	0
12	**I look forward with enjoyment to things:**		
		As much as I ever did	0
		Rather less than I used to	1
		Definitely less than I used to	2
		Hardly at all	3
13	**I get sudden feelings of panic:**		
		Very often indeed	3
		Quite often	2
		Not very often	1
		Not at all	0
14	**I can enjoy a good book or radio or TV program:**		
		Often	0
		Sometimes	1
		Not often	2
		Very seldom	3

Follow up Interview

B. BACKGROUND QUESTIONS I'll start by asking some questions about costs and extra visits or calls		
Q#	Question	Coding Category
A1	To confirm with you again: Are you doing paid work either full-time, part-time, doing casual work or are you self-employed or not working at all? *IF NOT WORKING AT ALL: SKIP A2 , ASK QA3*	1 = Working full-time 2 = Working part-time 3 = Casual worker 4 = Self-employed in own business 5 = Not working at all -99 = Refused -66 = Missing
A2	How much income from work, if any, did you lose by coming for your appointment here today?	Rands Refused Missing ___ ___ ___ -99 -66
A3	How much did it cost you to come to the clinic today (to come and to return)	Rands Refused Missing ___ ___ ___ -99 -66
A4	How many visits, including today's visit, did you make to the clinic since the last interview we did together *IF ONLY 1 VISIT, SKIP A5 AND ASK A6*	Visits Refused Missing ___ ___ -99 -66
A5	What did you need to talk about at this additional visit a. bleeding b. Pain c. Side effects e.g. Vomiting ,diarrhea d. Needed reassurance that the abortion was "on-track" e. Other *LISTEN TO CLIENT* *CIRCLE "1" IF MENTIONED* *CIRCLE '0' IF NOT MENTIONED*	No Yes Missing 0 1 -66 0 1 -66 0 1 -66 0 1 -66 0 1 -66 *SPECIFY* _____ _____
A6	Did you call the clinic since the last interview we did together *IF NO: SKIP TO SECTION B*	0 = No 1 = Yes -99 = Refused -66 = Missing
A7	How many times did you call the clinic since that interview	# of calls Refused Missing ___ ___ -99 -66

A8	What did you need to talk about during these phone calls? a. bleeding b. Pain c. Side effects e.g. Vomiting ,diarrhea d. Needed reassurance that the abortion was "on-track" e. Other *LISTEN TO CLIENT* *CIRCLE "1" IF MENTIONED* *CIRCLE '0' IF NOT MENTIONED*	No Yes Missing 0 1 -66 0 1 -66 0 1 -66 0 1 -66 0 1 -66 *SPECIFY* _____ _____
A9	How long do you think your (longest) call to the clinic lasted?	# of minutes Refused Missing ___ ___ -99 -66

B. **THIS MEDICAL ABORTION** Now I will ask you about your experiences with the abortion process, and about any information and counseling you received		
Q#	Question	Coding category
B1	**On this scale 0 is no bleeding and 10 is very heavy bleeding** **a. How much did you bleed when it was heaviest?** **b. How many days did the bleeding last altogether when you were using more than 1pad/day**	Number Refused Missing ___ ___ -99 -66 Days Refused Missing ___ ___ -99 -66
B2	**On this scale 0 is no pain and 10 is worst possible pain** **a. How bad was your pain when it was at its worst** **b. How long did this pain last**	Number Refused Missing ___ ___ -99 -66 Hours Refused Missing ___ ___ -99 -66
B3	**Did you experience the following side effects**	No Mild Moderate Severe Refused Missing
	a. Vomiting	0 1 2 3 -99 -66
	b. Dizziness	0 1 2 3 -99 -66
	c. Diarrhea	0 1 2 3 -99 -66
	d. Tiredness	0 1 2 3 -99 -66
	e. Headache	0 1 2 3 -99 -66
	f. Cold	0 1 2 3 -99 -66

	g. Sweating/hot/fever *READ OPTIONS*	0 0	1 1	2 2	3 3	-99 -99	-66 -66

These questions are to see if the information you were given prepared you for your experience **B4 – B7 : SAY "(OR SENT)" <u>ONLY</u> FOR MA + CELL PHONE GROUP**		
B4	**Did the information you were given (or sent) prepare you for the bleeding that you experienced** *READ OPTIONS*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing
B5	**Did the information you were given (or sent) prepare you for the pain you experienced** *READ OPTIONS*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing
B6	**Did the information you were given (or sent) prepare you for the side effects you experienced, if any** *READ OPTIONS*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing
B7	**From the information you were given (or sent) , were you able to understand what was happening during the abortion process** *READ OPTIONS*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing
B8	**Did the events of the abortion process go as you expected them to** *READ OPTIONS*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing

These questions are about general satisfaction		
B9	**How would you describe your overall satisfaction with your abortion?** *READ OPTIONS*	4 = Very satisfied 3 = Somewhat satisfied 2 = Somewhat dissatisfied 1 = Very dissatisfied -88 = Don't know -99 = Refused -66 = Missing
B10	**Would you recommend the abortion method you just experienced to a friend who needed an abortion at your stage of pregnancy?** *READ OPTIONS*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing
B11	**If you needed an abortion yourself at this stage of pregnancy in the future, would you want to have this same procedure again?** *READ* *OPTIONS*	1 = No Not at all 2 = No, Not really 3 = Yes, Somewhat 4 = Yes, Very Much -88 = Don't know -99 = Refused -66 = Missing

D1	**Shame**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D2	**Embarrassment**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D3	**Regret**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D4	**Guilt**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D5	**Anxiety**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D6	**Relief**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D7	**Fear of Disapproval**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D8	**Anger**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D9	**Depression**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D10	**Happiness**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D11	**Doubt**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd
D12	**Disappointment in Self**	1 Not at all	2 A little bit	3 Moderately	4 Quite a bit	5 Extremely	-66/-99 Msg/Refsd

		Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
ies1	**Any reminder brought back feelings about it**	0	1	2	3	4
ies2	**I had trouble staying asleep**	0	1	2	3	4
ies3	**Other things kept making me think about it**	0	1	2	3	4
ies4	**I avoided letting myself get upset when I thought about it or was reminded of it (4 = tried hard to avoid feeling upset)**	0	1	2	3	4
ies5	**I thought about it when I didn't mean to**	0	1	2	3	4
ies6	**I felt as if it hadn't happened or wasn't real**	0	1	2	3	4
ies7	**I stayed away from reminders about it**	0	1	2	3	4

ies8	**Pictures about it popped into my mind**	0	1	2	3	4
ies9	**I tried not to think about it (4 = tried hard not to think about it)**	0	1	2	3	4
ies10	**I was aware that I still had a lot of feelings about it, but I didn't deal with them**	0	1	2	3	4
ies 11	**My feelings about it were kind of numb**	0	1	2	3	4
ies12	**I found myself (acting or) feeling as though I was back at that time**	0	1	2	3	4
ies13	**I had waves of strong feelings about it**	0	1	2	3	4
ies 14	**I tried to remove it from my memory**	0	1	2	3	4
ies 15	**I had dreams about it**	0	1	2	3	4
ies 16	**I tried not to talk about it (4 = tried hard not to talk about it)**	0	1	2	3	4

J : PROVIDER EVALUATION OF ABORTION INTERVIEWER TO RECORD OUTCOME OF MA FROM CLIENTS FOLDER . ASK THE PROVIDER TO CHECK THIS SECTION		
	EVALUATION METHOD	**RESULT**
J: What method was used to assess the success of Medical Abortion CIRCLE ALL THAT APLY	J 1a. Ultrasound 1 = Yes/ 0 = No/ -66Msg	J1b 1 = Abortion complete 2 = Abortion Incomplete 3 = Pregnancy ongoing 4 = Other J1bcomment Comment_____
	J2a . Pregnancy Test 1 = Yes/ 0 = No/-66 Msg	J2b 1 = Positive 2 - Negative
	J3a. Clinical examination 1 = Yes/ 0 = No / -66 Msg	J3b Comment

SECTION K: SELF ASSESSMENT: ALL CLIENTS			CODE
K2. Did you bleed?	**Yes** **No**	**2a** **2b** ☐ ☐	Yes =1 No = 0 Missing = -66
K3. How many weeks pregnant were you when you took the pills at the clinic?	**4-6** **7-9**	**3a** **3b** ☐ ☐	4-6 = 1 7-9 = 2 Missing = -66
K4. Was the bleeding heavier than a normal period?	**Less** **Yes/same**	**4a** **4b** ☐ ☐	Less = 0 Yes/Same =1 Missing = -66
K5. Did you see any clots (lumps in the blood)?	**No** **Yes**	**5a** **5b** ☐ ☐	No = 0 Yes =1 Missing = -66
K6. It probably went fine.		**6** ☐	Ticked =1 Not ticked = -66
K7. Was the bleeding heavier than a normal period?	**Less** **Yes/same**	**7a** **7b** ☐ ☐	Less = 0 Yes/Same =1 Missing = -66
K8. Are you still bleeding like a normal period or more?	**No** **Yes**	**8a** **8b** ☐ ☐	No = 0 Yes =1 Missing = -66
K9. Sounds like you are still bleeding quite a bit. Make sure you tell the clinic staff about this.		**9** ☐	Ticked =1 Not ticked = -66
K10. Do you still feel pregnant?	**No** **Yes**	**10a** **10b** ☐ ☐	No = 0 Yes =1 Missing = -66
K11. Sounds like things went well.		**11** ☐	Ticked =1 Not ticked = -66
K12. Make sure you tell the clinic staff about this. They will be able to check what's happening.		**12** ☐	Ticked =1 Not ticked = -66

Appendix 5 Study 3 (Ethics)

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

14 April 2014

HREC REF: 677/2013

Ms D Constant
Public Health & Family Medicine
Women's Health Research Unit

Dear Ms Constant

PROJECT TITLE: THE USE OF LOW SENSITIVITY PREGNANCY TEST COMBINED WITH PHONE TEXT MESSAGES TO ASSESS EARLY MEDICAL ABORTION OUTCOME IN THE SOUTH AFRICAN PUBLIC SECTOR SETTING

Thank you for your response letter to the Faculty of Health Sciences Human Research Ethics Committee dated 7 April 2014.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th April 2015

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC reference no in all your correspondence.

Yours sincerely

Signed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix 6 Study 3 (Study Instruments)

Baseline Interview

IMVELAPHI / BACKGROUND		
Q#	**Question**	**Coding Category**
A1	**Mingaphi iminyaka yakho?** **How old are you?** [IF UNDER 18 YEARS → END INTERVIEW]	___ ___ **Iminyaka ngobudala / Age in years**
A2	**Uphuma koluphi uhlanga?** **Which population group do you belong to?**	1 = African 2 = Indian 3 = Coloured 4 = White 5 = Other [*SPECIFY*]: _____
A3	Uthetha oluphi ulwimi ekhaya? What is your home language?	1 = *isi*Xhosa 2 = Afrikaans 3 = English 4 = Other [*SPECIFY:* _____
A4	**Uhlala kweyiphi ingingqi?** **Which area do you live in?**	**_____**
A5	Uhambe ibanga elingakanani ukuza ekliniki namhlanje (uhambo olunye)? How far did you travel to come to the clinic today (1 way)?	1 = <10km 2 =10 – 20km 3 = 20 – 30km 4 = 30+km OR _____Imizuzu (mayibe mi 5 nangaphezulu) / minutes (must be 5 minutes or more)
A6	Uhlawule malini ukuza ekliniki namhlanje (ukuza nokubuya)? How much did it cost you to come to the clinic today (to come and to return)?	<u>In Rands:</u> ___ ___ . ___ ___
A7	<u>Uphumelele</u> eliphi ibanga eliphezulu lemfundo? What is the highest level of education that you have <u>completed?</u> ***[COMPLETE ONLY ONE ANSWER. IF P RESPONDS IN "STANDARD", CONVERT TO GRADE = STANDARD + 2]***	Ibanga / Grade: ___ ___ OR Ngaphezu konyaka webanga leshumi okanye ngaphezulu / Post-secondary of a year or more: 13 = Kholeji (umz. unobhalaokanye injineli) / College (e.g. secretarial or technical) 14 = Dyunivesiti / University

A8	**Ngowuphi umsebenzi ohlawulwayo owenzayo?** **What paid work do you have?** ***[CHOOSE ONE. If both working and a student, select code for work]***	**0 = Akaphangeli / Not working** **1 = Ngumfundi / Student /scholar** **2 = Likhesela/Owethutyana ohlawulwayo / Casual /Occasional paid work** **3 = Isigxina/ owexeshana ohlawulwayo / Steady Full-time/ part-time paid work**
A9	**Uhlala kwikhaya elinjani?** **What kind of home do you live in?** [READ CHOICES]	1 = Indlu yestena okanye iflethi/indawo yokuhlala abafundi / Formal house or flat/student accommodation 2 =Igumbi emzini womntu / Room in someone else's home 3= Ityotyombe/ ezimbacwini/indlu yamaplanga / Shack/informal dwelling/wendy house 4= Enye (nceda ucacise) / Other (*please specify*): _____
	IMBALI NGENZALO REPRODUCTIVE HISTORY	
B1	**Ukhulelwe kangaphi ebomini bakho kuquka esisisu?** **How many times have you been pregnant in your lifetime including this pregnancy?**	___ ___ Amatyeli wokhulelwa / Number of pregnancies
B2a-f	Zingaphi kwezizisu eziphelele ngoku: How many of these pregnancies resulted in: ***[READ ALL]*** a. Beleka ngesiqhelo / Normal vaginal birth b. Ngoqhaqho / Cesarean section c. Kukhupa isisu / Abortion [INCL TODAY'S] d. Kuphuncuka kwesisu / Miscarriage (spontaneous abortion) e. Kukhulelwa ethunjini Ectopic (tubal) pregnancy If c): Abortion = 2 or more f. Uzikhuphe kangaphi ngaphambili izisu ngamayeza / How many previous early medical abortions?	a. ___ ___ b. ___ ___ c. ___ ___ d. ___ ___ e. ___ ___ f. ___ ___
B5	Sekhe walenza uhlolo lokhulelo endlini? Have you ever taken a home pregnancy test?	0 = Hayi / No 1 = Ewe / Yes
B3a B3b	[DO NOT ASK THIS, EXTRACT FROM CLIENT FOLDER] **Gestational age by Ultrasound at this TOP**	**___ W ___ D** **GA weeks days**
B4	Date of this Ultrasound	(dd/mm/yy)_____
	C. FAMILY PLANNING	

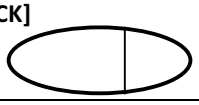
CC5	Indlela ehlala ixesha elide yocwangciso ntsapho yile ehlala unyaka nangaphezulu. Zeziphi iindlela ezihlala ixesha elide zocwangciso ntsapho ozaziyo? A long lasting contraceptive method is one that lasts for a year or more. What long lasting contraception methods do you know of? her ***[DO NOT READ OPTIONS. LISTEN TO CLIENT: CIRCLE "1" IF MENTIONED, CIRCLE "0" IF NOT MENTIONED]***	CACISA / SPECIFY _____
C1a-j	Kwinyanga ezi li- 12 ezidlulileyo usebenzise eyi/eziphi indlela zo cwangciso ntsapho? In the past 12 months what family planning method/s have you used? ***[DO NOT READ LIST. CIRCLE YES FOR ALL THAT APPLY.*** ***PROMPT: Ikhona enye indlela?*** ***Any other method?]***	No method 0 = No/ 1 = Yes Depo /Nur Isterate 0 = No/ 1 = Yes Oral Pills 0 = No/ 1 = Yes IUD/Copper T/Mirena 0 = No/ 1 = Yes Implant 0 = No/ 1 = Yes Emergency Pill 0 = No/ 1 = Yes Male condom 0 = No/ 1 = Yes Female condom 0 = No/ 1 = Yes Other method 0 = No/ 1 = Yes Other method: specify_____ Dual method 0 = No/ 1 = Yes Dual method: specify:_____ +_____
C2a-l	Yeyiphi enye indlela ukuba ikhona, obuyisebenzisa njengoko uye wakhulelwa ngoku? What method if any, were you using when you became pregnant now? ***[CHOOSE ONLY ONE ANSWER.]***	No method Depo /Nur Isterate Oral Pills IUD/Copper T/Mirena Implant Emergency Pill Male condom Female condom Other method Other method: specify_____ Dual method Dual method: specify:_____+_____
[SHOW THE PARTICIPANT THE MOBISITE EITHER ON YOUR PHONE OR ON THE IPAD. LET HER SPEND UP TO 10 MINUTES BROWSING THROUGH IT. THEN ASK THE FOLLOWING QUESTIONS]		
C3	Ufunde lukhulu ngendlela zocwangciso ntsapho ngokufunda i(ichoosewhen mobisite)? Did you learn more about contraception methods by reading the ichoosewhen mobisite?	0 = Hayi / No 1 = Ewe / Yes
C4a-j	Yeyi\zeziphi indlela ofunde ngazo ku (ichoosewhen mobisite)? What method/s did you read about in the ichoosewhen mobisite? ***[Circle what was mentioned (Don't prompt or read responses aloud)]***	No new method 0 = No/ 1 = Yes Depo /Nur Isterate 0 = No/ 1 = Yes Oral Pills 0 = No/ 1 = Yes IUD/Copper T/Mirena 0 = No/ 1 = Yes Implant 0 = No/ 1 = Yes Emergency Pill 0 = No/ 1 = Yes Male condom 0 = No/ 1 = Yes

		Female condom 0 = No/ 1 = Yes Other method 0 = No/ 1 = Yes Other specify:_____
C5a C5b	Loluphi olona lwazi onokulusebenzisa olufundileyo? What was the most useful information you read? ***[Don't prompt]***	Method _____ New information: _____ _____ _____ _____
C6a C6b	Loluphi olunye olona lwazi lusondeleyo onokulusebenzisa? What was the most next most useful information? ***[Don't prompt]***	Method _____ New information: _____ _____ _____ _____
C7	Yeyiphi indlela ocinga ukuba ungayisebenzi emva kokuba ukhuphe isisu? What method do you think you will choose to use after your abortion?	_____ _____ _____ _____
UKUSEBENZISA UNOMYAYI CELL PHONE USAGE		
D1	Ingaba usebenzisa I prepaid okanye icontract? Are you on prepaid or contract?	1 = Prepaid or contract with TOP UP 2 = Contract (cannot get prepaid airtime)
D2	Usoloko unawo umoya? Do you usually have airtime? ***[LISTEN TO CLIENT AND CIRCLE BEST OPTION PROBE IF NECESSARY]***	1 = Ndisoloko ndinomoya / I always have airtime 2 = Khe ndiphelelwe kodwa ndikhawuleze ndiwufake / I run out but top-up immediately 3 = Ngamanye amaxesha ndiba nawo ngamanye ndingabi nawo / Sometimes I have airtime and sometimes I don't 4 = Okunye / Other Cacisa / Specify: _____
D3	Kukangakanani ukuba abantu banga bona imiyalezo SMSs oyifumanayo? How likely is it that people would see SMSs that you get? ***[READ CHOICES]***	1 = Kungenzeka kakhulu / Very likely 2 = Kusenokwenzeka / Might happen 3 = Akunakwenzeka / Not likely 4 = Ngekhe / Never
D4	Ingaba uyayisebenzisa i(internet) kwifowuni yakho? Do you use the internet on your phone?	2 = Ewe. Qho / Yes. Often 1 = Ewe, kuphela ngamanye amaxesha / Yes, only sometimes 0 = Hayi / No
D5	Ingaba uyamsebenzisa u Mxit kwifowuni yakho? Do you use Mxit on your phone?	2 = Ewe. Qho / Yes. Often 1 = Ewe, kuphela ngamanye amaxesha / Yes, only sometimes

		0 = Hayi / No

SECTION A,B AND C TO BE DONE BEFORE PARTICIPANT SEES THE PROVIDER		
C. IMIBUZO NGEMVELAPHI BACKGROUND QUESTIONS Ndizakuqalisa ukukubuza imibuzo ngamaxabiso utyelelo olongeziweyo kunye nokufowuna I'll start by asking some questions about costs and extra visits or calls		
Q#	Question	Coding Category
A1	Utyelele kangaphi ekliniki, (NGAPHANDLE kwanamhlanje) ukusukela kudliwano ndlebe ebesinalo kunye? How many other visits, (EXCLUDING today's visit), did you make to the clinic since the last interview we did together? ***If 0, skip to A3***	Visits: _____
A2	Yintoni obufuna ukuthetha ngayo kolutyelelo longeziweyo? What did you need to talk about at this additional visit? a. Ukopha / bleeding b. Intlungu / Pain c. Imiphumela umz. Ukugabha, ukuhambisa / Side effects e.g. Vomiting ,diarrhea d. Ubufuna isiqinisekiso sokuba ukhupho sisu "lusahamba kakuhle" / Needed reassurance that the abortion was "on-track" e. Okunye / Other ***[LISTEN TO CLIENT*** ***CIRCLE "1" IF MENTIONED*** ***CIRCLE '0' IF NOT MENTIONED]***	a. 0 = Hayi / No 1 = Ewe / Yes b. 0 = Hayi / No 1 = Ewe / Yes c. 0 = Hayi / No 1 = Ewe / Yes d. 0 = Hayi / No 1 = Ewe / Yes e. 0 = Hayi / No 1 = Ewe / Yes CACISA / SPECIFY _____
A3	Ukhe wafowunela ekliniki ukusukela kudliwano ndlebe ebesinalo kunye? Did you call the clinic since the last interview we did together? ***IF NO: SKIP TO SECTION B***	0 = Hayi / No 1 = Ewe / Yes
A4	Ufowunele kangaphi ekliniki ukusuka kolwadliwano ndlebe? How many times did you call the clinic since that interview?	# of calls: _____
A5	Ubufuna ukuthetha ngantoni ngelixa ubufowuna? What did you need to talk about during these phone calls? a. Ukopha / bleeding b. Intlungu / Pain c. Imiphumela umz. Ukugabha, ukuhambisa / Side effects e.g. Vomiting ,diarrhea	a. 0 = Hayi / No 1 = Ewe / Yes b. 0 = Hayi / No 1 = Ewe / Yes c. 0 = Hayi / No 1 = Ewe / Yes d. 0 = Hayi / No 1 = Ewe / Yes e. 0 = Hayi / No 1 = Ewe / Yes

	d. Ubufuna isiqinisekiso sokuba ukhupho sisu "luhambe kakuhle" / Needed reassurance that the abortion was "on-track" e Ukutshintsha idinga / Reschedule appointment. f. Okunye / Other ***[LISTEN TO CLIENT*** ***CIRCLE "1" IF MENTIONED*** ***CIRCLE '0' IF NOT MENTIONED]***	f. 0 = Hayi / No 1 = Ewe / Yes CACISA / SPECIFY _____
B. THIS MEDICAL ABORTION Ngoku ndiza kubuza ngolu khupho sisu. Now I will ask you about this abortion.		
B1	Kwesi sikali O ukungophi 10 ukopha kakhulu. On this scale 0 is no bleeding and 10 is very heavy bleeding. a. How was the bleeding when it was heaviest? Wophe kangakanani apho wophe kakhulu? b. Wophe intsuku ezingaphi zizonke apho usebenzise ngaphezu kwepad enye ngosuku? How many days did the bleeding last altogether when you were using more than 1pad/day?	a. Number: _____ b. Days: _____
B2	Ingaba isenzo sokhupho sisu ekhaya sihambe ngendlela obuyilindele ukuba ibe njalo? Did the events of the abortion process at home go as you expected them to? ***[READ OPTIONS]*** ***IF 3. YES, SOMEWHAT OR 4. YES, VERY MUCH, SKIP TO B4***	1 = Hayi kwaphela / No, not at all 2 = Hayi, ncam / No, not really 3 = Ewe, nje / Yes, somewhat 4 = Ewe, kakhulu / Yes, very much
B3	Yintoni obungayilindelanga? What was unexpected?	_____ _____
Ngoku ndiza kubuza ngemiyalezo SMSs, uhlolo lokhulelo kunye ne'checklist. **Now I'll ask you about the SMSs, the pregnancy test and the checklist.**		
B4a	Ingaba imiyalezo ikuncedile na kolu khupho sisu lwakho? Did the SMSes help you through your abortion? ***IF 3. DISAGREE OR 4. STRONGLY DISAGREE, GO TO B5.***	1 = Ndiyavuma kakhulu / Strongly agree 2 = Ndiyavuma / Agree 3 = Andivumi / Disagree 4 = Andivumi kwaphela / Strongly disagree 0 = Participant did not receive any SMSes → **B6a**
B4b	Ungandixelela kabanzi ukuba ikuncede njani lemiyalezo?	_____ _____

	Can you tell me more about how the SMSs helped you?	
B5	Ubunexhala malunga nemfihlo (ukuba omnye umntu angabona lemiyalezo)? Were you worried about privacy (that someone might see the SMSs)?	1 = Ndiyavuma kakhulu / Strongly agree 2 = Ndiyavuma / Agree 3 = Andivumi / Disagree 4 = Andivumi kwaphela / Strongly disagree
B6a	Ulenzile uhlolo lokukhulelwa ekhaya? Did you do the home pregnancy test? **IF YES, GO TO B6b1.**	0 = Hayi / No 1 = Ewe / Yes
B6b	Kutheni? Why not? ***[SKIP TO B10a, AND have ppt do test at the end of this interview.*** ***After test; complete questions B6b1 – B8]***	_____ _____ _____
B6b1	When did you take the pregnancy test? Ulwenze nini uhlolo lokhulelo?	Date: **(dd/mm/yy)_____**
B6c	**[LOOK AT PARTICIPANT SKETCH/PHOTO OF TEST AND CIRCLE ANSWER (DO NOT ASK QUESTION)** **<u>IF PHONE INTERVIEW:</u> ASK HER TO DESCRIBE SKETCH** **<u>IF CLINIC INTERVIEW AND SHE FORGOT TO BRING THE SKETCH:</u> ASK HER TO DO THE SKETCH IN THIS BLOCK]** 	Participant Test picture/photo has 1 = 1 line: in control (small) window 2 = 2 lines: 1 in test + 1 in control window 3 = 1 line: in test (big) window 4 = Other SPECIFY_____
B7	Ukufumene kunjani <u>ukwenza</u> uhlolo? How did you find <u>doing</u> the test? ***[If 3. Easy or 4. Very easy, skip to B8]***	1 = Kunzima kakhulu / Very difficult 2 = Kunzima / Difficult 3 = Kulula / Easy 4 =Kulula kakhulu / Very easy
B7a	Yintoni eyayinzima ekwenzeni uhlolo?/ What was difficult about doing the test?	_____ _____
B8	Zithini iziphumo zakho zohlolo? What was your test result? ***[READ OPTIONS AND CLARIFY WHEN NEEDED]***	1 = Iziphumo zi negative = luphumelele ukhupho sisu / The test was negative -= successful abortion 2 = Iziphumo zi positive lusaqhubeka ukhulelo / The test was positive = ongoing pregnancy 3 = Iziphumo zinengxaki / The test was faulty 4 = Okunye Other CACISA / SPECIFY_____
B10a	Uyenzile ichecklist? Did you do the checklist? **IF YES, GO TO B11.**	0 = Hayi / No 1 = Ewe / Yes

B10b	Kutheni? Why? ***SKIP TO CC2, AND have participant do checklist after the pregnancy test at end of this section of the interview. She should complete the checklist as she remembers she felt on day 13 following the MTOP—not how she feels today.*** ***Then complete these questions B11 – B13***	_____ _____ _____ _____
B11	**COPY FROM CHECKLIST ONTO THIS FORM. IF PARTICIPANT DID CHECKLIST AND FORGOT TO BRING IT, ASK HER WHAT SHE WROTE DOWN ON DAY 13.** Zithini iimpendulo zakho zechecklist? What were your checklist answers? a) Ukuba ubunempawu zokhulelo ngaphambili, zimkile? / If you had pregnancy symptoms before, are they gone? b) Iziphumo zibonise ukungakhulelwa / Did the pregnancy test show negative?) Wophe kakhulu intsuku ezi-2 nangaphezulu / Did you bleed heavily for 2 or more days d) Usopha na? / Are you still bleeding? e) Ukuba ewe, ngaphezu kwesiqhelo? / If yes, more than heavy period? f) Unamazantsi wesisu / Do you have severe abdominal cramps? g) Ingaba iziphumo zibonise ukukhulelwa / Did the pregnancy test show positive? h) Uziva ugula? / Do you feel sick? i) Ubu nomkhuhlane? / Have you had a fever? j) Uziva ubuthathaka/umzimba ubuhlungu? / Do you feel weak/the whole body is aching?	a. 0 = Hayi / No 1 = Ewe / Yes 2 = Zange ndibe neempawu zokhulelwa / Never had pregnancy symptoms b. 0 = Hayi / No 1 = Ewe / Yes c. 0 = Hayi / No 1 = Ewe / Yes d. 0 = Hayi / No 1 = Ewe / Yes e. 0 = Hayi / No 1 = Ewe / Yes f. 0 = Hayi / No 1 = Ewe / Yes g. 0 = Hayi / No 1 = Ewe / Yes h. 0 = Hayi / No 1 = Ewe / Yes i. 0 = Hayi / No 1 = Ewe / Yes j. 0 = Hayi / No 1 = Ewe / Yes
B12	Ingaba iziphumo zechecklist zithetha ukuba mawubuyele ekliniki? Did the checklist result mean you should return to the clinic?	0 = Hayi / No 1 = Ewe / Yes 3 = Okunye/ Other **If other:** CACISA / SPECIFY_____
B13	Kutheni ufuneke ubuyele ekliniki? Why did you NEED to return to the clinic? ***[Read each option aloud]*** a) ..Participant did not return. **[Do not read a) aloud. If 1. Yes, skip to CC2]** b) Ndifune ukubuyela uphando / I needed to return for the study.	a) 0 = Hayi / No 1 = Ewe / Yes b) 0 = Hayi / No 1 = Ewe / Yes

	c) Ngenxa yeziphumo zohlolo lokhulelo / Because of my pregnancy test result.	c) 0 = Hayi / No 1 = Ewe / Yes
	d) Bendifuna ukuqiniseka kumnikezinkonzo ukuba andikhulelwanga / I wanted reassurance from the provider that I am no longer pregnant.	d) 0 = Hayi / No 1 = Ewe / Yes
	e) Bendifuna ukuzocwangcisa / I needed contraception.	e) 0 = Hayi / No 1 = Ewe / Yes
	f) Umnikezinkonzo uthe zendibuye / The provider asked me to return.	f) 0 = Hayi / No 1 = Ewe / Yes
	g) Enye / Other	g) 0 = Hayi / No 1 = Ewe / Yes
	h) Ukuba enye, cacisa. / If other, specify.	_____ _____ _____

Uqale ukujonga I'mobisite m.ichoosewhen' kwi ipad(efowunini) kudliwano ndlebe lwethu lokuqala ngexesha wawuze ekliniki:
You first looked at the mobisite m.ichoosewhen on the ipad (phone) at our first interview when you came to the clinic:

CC2	Ingaba ulwazi olufunde kwi 'm.ichoosewhen lukwenze wakhetha indlela yocwangciso ntsapho ethile? Did reading m.ichoosewhen information influence your choice of contraception method?	0 = Hayi / No 1 = Ewe / Yes
CC3	Ingaba ukufunda I m.ichoosewhen ikuncede ukuba ufunde ngakumbi malunga neendlela zocwangciso ntsapho? Did reading m.ichoosewhen help you learn more about contraception methods?	0 = Hayi / No 1 = Ewe / Yes
CC4	Imiyalezo ikukhuthaze ukuba ufunde ulwazi kwi m.ichoosewhen ngocwangciso ntsapho efowunini yakho okanye kwi internet. Ingaba uye waphinda wayifunda I m.ichoosewhen ukusukela kudliwano ndlebe lwethu lokugqibela? The SMSs encouraged you to read the m.ichoosewhen contraception information on your phone or the internet. Did you read m.ichoosewhen again since our last interview?	0 = Hayi / No 1 = Ewe / Yes
CC5	Imiyalezo ikukhumbuze ngendlela ezi-2 ezihlala ixesha elide zocwangiso ntsapho. Indlela ehlala ixesha elide yocwangciso ntsapho yile ehlala unyaka nangaphezulu. Zeziphi iindlela ezihlala ixesha elide zocwangciso ntsapho ozaziyo? / The SMSs also reminded you of 2 long lasting contraceptive methods. A long lasting contraceptive method is one that lasts for one year or more. What long lasting contraception methods do you know of? a. The IUD (CopperT, Mirena, or "loop") b. Implant c. Other ***[DO NOT READ OPTIONS. LISTEN TO CLIENT: CIRCLE "1" IF MENTIONED, CIRCLE "0" IF NOT MENTIONED]***	a. 0 = Hayi / No 1 = Ewe / Yes b. 0 = Hayi / No 1 = Ewe / Yes c. 0 = Hayi / No 1 = Ewe / Yes CACISA / SPECIFY _____

STOP HERE. SECTIONS C AND D TO BE COMPLETED AFTER PARTICIPANT HAS SEEN THE PROVIDER AND BEEN ASSESSED.

Lemibuzo imalunga nocwangciso ntsapho kunye nokwaneliseka jikelele. These questions are about contraception and general satisfaction.		
C1a	Yeyiphi indlela yocwangciso ntsapho oye wayiqala emva kolu khupho sisu? What contraceptive method/s did you start after this abortion? **[CIRCLE ONE RESPONSE ONLY]** ***SKIP TO D1 IF NO METHOD***	a. No method b. Depo /Nur Isterate c. Oral Pills d. IUD/Copper T/Mirena e. Implant ~~f. Emergency Pill~~ g. Male condom only h. Female condom only i. Other method j. Other method: specify_____ ___ k. Dual method l. Dual method: specify:_____ +_____
C1b	Uqale nini? When did you start?	1 = Namhlanje / Today 2 = Kwikliniki yokhupho sisu apho ndiqale khoma ukhupho sisu ngamayeza / At the abortion clinic when I started the MA 3 = Kwenye ikliniki / Other clinic
Le mibuzo imalunga nokuzilawula nokwaneliseka jikelele. **This question is about self-management and general satisfaction.**		
D1	Ukuba wena ubufuna ukhupho sisu kwesisigaba sokukhulelwa kwixa elizayo, ubunokhetha ukwenza ntoni ukuhlola ukuba ukhupho sisu lwakho luyimpumelelo: If you needed an abortion yourself at this stage of pregnancy in the future, what would you prefer to do to check your abortion is successful? **[NB: THIS IS PRIMARY OUTCOME OF STUDY: ENSURE PPT UNDERSTANDS OPTIONS]**	1 = Uze ekliniki ukuzo hlolwa / Come to the clinic for assessment 2 = Uhlolo lokhulelwa KUPHELA(uze ubuyele xa ufuna) / Pregnancy test ONLY (and come back if I need to) 3 = Uhlolo lokukhulelwa kunye nechecklist KUPHELA (uze ubuyele xa ufuna) / Pregnancy test and checklist ONLY (and come back if I need to) 4 = Uhlolo lokukhulelwa kwaye ufumane IMIYALEZO(uze ubuyele xa ufuna) / Pregnancy test and get SMSs (and come back if I need to) 5 = Uhlolo lokukhulelwa kunye nechecklist kwaye ufumane IMIYALEZO(uze ubuyele xa ufuna) / Pregnancy test and checklist and get SMSs (and come back if I need to) 6 = Enye yezi zingentla uze ufownele ekliniki ukuqinisekisa / 1 of above and phone the clinic if I need to SPECIFY which_____
D2	Ungalu chaza njani ulwaneliseko lwakho lulonke malunga nokhupho sisu lwakho? How would you describe your overall satisfaction with your abortion?	4 = Ukwaneliseka kakhulu / Very satisfied 3 = Ukwaneliseka nje / Somewhat satisfied 2 = Ukunganeliseki nje / Somewhat dissatisfied 1 = Ukunganeliseki / Very dissatisfied
D3	Ungamxelela umhlobo malunga nendlela yokhupho sisu osanda ukuyenza ofuna ukukhupha isisu njengawe? Would you recommend the abortion method you just experienced to a friend	1 = Hayi kwaphela / No, not at all 2 = Hayi, ncam / No, not really 3 = Ewe, nje / Yes, somewhat 4 = Ewe, kakhulu / Yes, very much

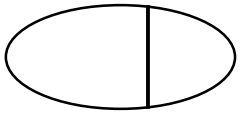
	who needed an abortion at your stage of pregnancy?	
D4	Ukuba wena ubufuna ukhupha isisu kwesisigaba sokhulelo kwixa elizayo, ubunokufuna ukwenza kanye ngale ndlela kwakhona? If you needed an abortion yourself at this stage of pregnancy in the future, would you want to have this same procedure again?	1 = Hayi kwaphela / No, not at all 2 = Hayi, ncam / No, not really 3 = Ewe, nje / Yes, somewhat 4 = Ewe, kakhulu / Yes, very much

E: PROVIDER EVALUATION OF ABORTION INTERVIEWER TO RECORD OUTCOME OF MA FROM WOMAN'S FOLDER. ASK THE PROVIDER TO CHECK THIS SECTION. IF PARTICIPANT NEVER RETURNS TO THE CLINIC, THIS SECTION MAY BE LEFT BLANK.		
	E0. Provider Initials: ___ ___ E0a. Date Section E completed: _____	
What method was used to assess the success of Medical Abortion	**E1a. Ultrasound** 1 = Yes → **E1b** 0 = No → **E2a**	E1b. Based on ultrasound ONLY, abortion assessment was: **1 = Pregnancy ended (abortion is complete; may see some retained products)** **2 = Pregnancy ongoing (pregnancy is still viable and growing)** **3 = Pregnancy ended BUT Retained sac or retained non-viable pregnancy (do not include retained products only—see 1)** 4 = Other. SPECIFY _____
	E2a. High sensitivity Pregnancy Test by provider? 1 = Yes → **E2b** 0 = No → **E3a**	E2b. What was the result? **1 = Positive** 2 = Negative
	E3a. Clinical examination (including blood pressure, pelvic exam, etc.)? 1 = Yes → **E3b** 0 = No → **E4a**	E3b. **Comments (e.g. related to abortion, temperature, hb, etc.)** _____ _____
	E4a. **Clinical History** 1 = Yes → **E4b** 0 = No → **E4c**	E4b. **Comments (e.g. bleeding, still bleeding, pain, infection symptoms):** _____ _____
	E4c. Based on the information provided in E1-E4, abortion assessment was:	**1 = Pregnancy ended (abortion is complete)** **2 = Pregnancy ongoing (pregnancy is still viable and growing)** **3 = Pregnancy ended BUT Retained sac or retained non-viable pregnancy (do not include retained products only)** 4 = Other SPECIFY _____

Treatment Given	**E5a. Additional Surgical (MVA) done** 1 = Yes → **E5b** 0 = No → **E6a**	**E5b. Reason:** _____ _____
	E6a. Extra Medication given: 1 = Yes→**E6b** 0 = No→**E7a**	**E6b. Reason**:_____ **E6c. Antibiotics?** 0 = No / 1 = Yes **E6d. Misoprostol?** 0 = No / 1 = Yes **E6e. Other medication?** 0 = No / 1 = Yes SPECIFY_____
Additional clinic visit	**E7a. Was participant was asked to return to the clinic in addition to regularly scheduled follow-up?** 0 = No → **go to signature and end form** 1 = Yes → **E7b**	**E7b. Reason:**_____
	E7c. Did participant attend this additional visit?	0 = No 1 = Yes

Self- Assessment Checklist

Remember to take your special pregnancy test 13 days after your first appointment. Draw what you see in the window of your special pregnancy test below.



Then respond to the following questions.

Checklist MA Home Assessment

Abortion is complete (when both are ticked Yes)

If you had any pregnancy symptoms before, are they gone? No ☐ Yes ☐

☐ Never had pregnancy symptoms

Did you bleed heavily for 2 or more days? No ☐ Yes ☐

Contact the clinic (when 1 or more are ticked Yes)

Are you still bleeding more than a normal period? No ☐ Yes ☐

Do you have severe abdominal cramps? No ☐ Yes ☐

Did the pregnancy test show positive? No ☐ Yes ☐

Do you feel sick? No ☐ Yes ☐

Do you have a fever? No ☐ Yes ☐

Do you feel weak/ the whole body is aching? No ☐ Yes ☐

Save this paper and bring it to your follow-up appointment.

Appendix 7 Study 4 (Ethics)

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/research/humanethics/forms

19 September 2013

HREC REF: 321/2013

Ms D Constant
Women's Health Research Unit
Room 3.39, level 3
Falmouth Building

Dear Ms Constant

PROJECT TITLE: EVALUATING MEDICAL INDUCTION TERMINATION SERVICES IN THE WESTERN CAPE PROVINCE

Thank you for your letter to the Faculty of Health Sciences Human Research Ethics Committee dated 23 August 2013.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th September 2014

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC. REF in all your correspondence.

Yours sincerely

Signed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

s.thomas

Appendix 8 Study 4 (Study Instruments)

Second trimester TOP services in Western Cape Province: Data Collection
Interview 1 : End Client Questionnaire (ECQ)

NO.	QUESTIONS	CODING CLASSIFCATION	
001	Age (from EC)	|_____|_____| YEARS	
001N	How would you identify yourself?	African……..1 White …….. 2 Coloured……..3 Indian …….. 4 Other …….. 5 Other: Specify_____	
002	What language(s) do you speak *(mark all that apply)*		
	a. Afrikaans	Yes……1 / No…..2	
	b. English	Yes……1 / No…..2	
	c. Xhosa	Yes……1 / No…..2	
	k. Other	Yes……1 / No…..2	
	Other: Specify	_____	
002N	What is your home language?	Afrikaans ……..1 English ……..2 Xhosa …….. …….. ……..3 Other …….. 4 Other: Specify_____	
003NEW	What is the highest level of education that you have completed? (Probe as necessary. NB: If standard or grade; Grade = Standard + 2)	None – Grade 5 .....1 Grade 6-8 .....2 Grade 9-11 .....3 Grade 12 (matric) .....4 Diploma .....5 Degree (BA, Bcom, etc) .....6 Masters .....7 Doctoral 8	
004	Are you currently in school or university?	Yes……1 / No…..2	

NO.	QUESTIONS	CODING CLASSIFCATION	
005	What type of housing do you live in?	House .....1 Flat .....2 Shack .....3 Cottage / Wendy House (behind another house).....4 Student residence..... 5 Other. .....6 Other: Specify_____	
005b	What neighborhood do you live in	LIST: _____	
006	How many rooms are there where you currently live?	Number: _____	
006N	How many rooms are there where you currently live (excluding bathrooms, halls and passages)?	Number: _____	
006aN	What is the most often used source of drinking water at the place where you stay?	Piped – in the home ……1 Piped – tap in own yard/garden …….2 Piped - public tap/kiosk (free) ……. 3 Piped - public tap/kiosk (paid for) ….4 Other water source ……..5 Other: Specify_____	
006bN	Is the place where you stay connected to an electricity supply?	Yes……1 / No…..2	
006cN	Is there an inside toilet where you stay?	Yes……1 / No…..2	
007	How many adults and children including yourself are living there?	a) Adults: _____ b) Children: _____ Total: _____	
007N	How many adults and children including yourself have stayed there at least 15 out of the last 30 days?	a) Adults: _____ b) Children: _____ Total: _____	
008	Do you do any kind of work that you get paid for?	Yes……1 / No…..2	
008aN	How would you describe your employment situation? INTERVIEWER, read ALL options, choose one.	Unable to work……1 Unemployed……. …….2 Self-employed ……. …… 3 Employed ……. …….4 Other ……. …….5 Other: Specify_____	

NO.	QUESTIONS	CODING CLASSIFCATION	
008a2N 008a2aN 008a3N	Are you the head of the household (or the primary "bread winner") in your house? IF 008a2N=NO, Is the primary bread winner in your house a…(READ OPTIONS): IF 008a2N=NO: How would you describe the employment situation of the primary breadwinner in your household? INTERVIEWER, read ALL options, choose one.	Yes……1 / No…..2 Man……1 / Woman…..2 Unable to work……1 Unemployed…… ……2 Self-employed …… …… 3 Employed …… …….4 Other …… …….5 Other: Specify_____	
008bN	What has been your primary source of income (or money) in the last 12 months? *(READ OPTIONS; CHOOSE ONE)*	None……1 Family ……2 Employment ……3 Spouse, boyfriend, girlfriend ……. 4 Grant/government subsidy…… 5 Other …… 6 Other: Specify_____	
008b2N	I'd like to know what the total income for you and the people in your house is. This will help us to understand whether getting health care services is sometimes a burden for you. Can you tell me: What is the total income that you and the other people that live in your house receives in an average month from employment, grants or other sources (e.g. a family member who regularly gives you money, informal employment, etc.)?	Average monthly household income: From employment: _____ From grants of any kind: _____ Other sources: _____ Total: _____	
008cN	a. Are you currently caring financially for any dependents? *b. IF YES:* Are your dependents children (<18 years), adults, or both?	Yes……1 / No…..2 Children only ……..1 Adults only ……..2 Both children and adults ……..3	

NO.	QUESTIONS	CODING CLASSIFCATION	
008dN	Do the people in your household go without food often, sometimes, seldom, or never?	Often……1 Sometimes……..2 Seldom ……3 Never ……..4	
I am now going to ask you about pregnancies.			
009	How many times have you been pregnant in your lifetime? (INCLUDE THE PREGNANCY THAT ENDED IN THIS TOP)	Number: _____	
010	How many of these pregnancies resulted in: Ukuzala ngendlela yesiqhelo ebufazini	Number: _____	
	b) Ukuzala ngesiza/ngoqha	Number: _____	
	c) Ukhupho sisu (UKUQUKA UKHUPHO SISU LWANAMHLANJE)	Number: _____	
	c ii) IF PRIOR TOP Where did you have your TOP last time?	OPEN RESPONSE	
	d) Ukuphuma kwesisu (spontaneous abortion)	Number: _____	
	e) Ukumithela ethunjini (tubal) pregnancy	Number: _____	
011	How many weeks pregnant were you before this TOP today?	Number of weeks: _____	
I will now ask you about family planning.			
410	Have you or your partner ever used a family planning method before today?	Yes……1 / No…..2	
411NEW	What family planning methods have you used in the past (before today)? E.g. condoms; no sex or anything else? Interviewers: CIRCLE “Yes” if mentioned “No” if not mentioned		
	a) Abstinence…	Yes……1 / No…..2	
	d) IUD/loop/copper T	Yes……1 / No…..2	
	e) Injection	Yes……1 / No…..2	
	f) Pills	Yes……1 / No…..2	
	g) Male condoms	Yes……1 / No…..2	
	h) Emergency contraception	Yes……1 / No…..2	
	i) Female condoms	Yes……1 / No…..2	
	j) Other methods	Yes……1 / No…..2	
	Other: Specify_____		

NO.	QUESTIONS	CODING CLASSIFCATION	
411aN	Were you using a family planning method <u>when you became pregnant this time? If YES, what method were you using?</u> Interviewers: Do NOT prompt CIRCLE "Yes" if mentioned "No" if not mentioned	Yes……1 / No…..2	
	a) Abstinence	Yes……1 / No…..2	
	d) IUD/loop/copper T	Yes……1 / No…..2	
	e) Injection	Yes……1 / No…..2	
	f) Pills	Yes……1 / No…..2	
	g) Male condoms	Yes……1 / No…..2	
	h) Emergency contraception	Yes……1 / No…..2	
	i) Female condoms	Yes……1 / No…..2	
	j) Other methods	Yes……1 / No…..2	
	Other: Specify_____		
411bN	If NO, why not? Interviewers: Do NOT prompt CIRCLE "Yes" if mentioned "No" if not mentioned (Tick all that apply)		
	Don't know	Yes……1 / No…..2	
	Didn't know about family planning methods	Yes……1 / No…..2	
	Fear/Dislike of side effects	Yes……1 / No…..2	
	Religious reasons	Yes……1 / No…..2	
	Partner does not approve	Yes……1 / No…..2	
	Family member does not approve	Yes……1 / No…..2	
	Cost	Yes……1 / No…..2	
	Other,	Yes……1 / No…..2	
	Other, Specify_____		
412	a) Before today, have you ever <u>heard about</u> emergency contraceptive pills (also known as the "morning after pill" or ECPs) to prevent pregnancy after unprotected sex?	Yes……1 / No…..2 / Don't know…..9	
	b) In the past year, <u>have you used</u> emergency contraceptive pills?	Yes……1 / No…..2 / Don't know…..9	

Thank you very much for your participation in this research.

Interview 2

I will now ask about how far you have travelled to come here and how much it cost you to have this TOP

012	How far from your home did you travel to come to this facility for the TOP that you had here?	A.Distance in kilometers: ☐☐☐☐ OR, IF SHE DOESN'T KNOW THE DISTANCE: B.Time: ☐☐.☐☐ hh mm	
013	a) How much does it cost you to come here – I mean for you to come from and return home?	R_____	
	b) How much does it cost, if anything, to pay for child care while you are away from home for the TOP?	R_____	
	c) Are you missing work (either paid or unpaid) while you have been here for the TOP?	Yes……1 / No…..2	
	d) How much income from work, if any, did you lose to come here for the TOP?	R_____	
	) Are t e) Are there any other costs that you have had as a result of the TOP that you would like to mention? (PROBE: Any payments you made to other doctors or nurses at other facilities before today? Pharmacy/chemist for medicines? Pads or other supplies?)	Yes……1 / No…..2	
		Item 1.	
		Cost 1. R	
		Item 2..	
		Cost 2. R	
		Item 3 .	
		Cost 3.. R	
014	Did anyone help you to pay for the expenses related to your abortion?	Yes……1 / No…..2	
	a) IF YES, Who was that?		
	Husband	Yes……1 / No…..2	
	Partner	Yes……1 / No…..2	
	Family member	Yes……1 / No…..2	
	Friend	Yes……1 / No…..2	
	Other	Yes……1 / No…..2	
	If Other : Specify	_____	
	b) How did s/he help with the expenses? (PROBE: Did s/he give you money? How much? What did s/he help with or pay for?)	OPEN RESPONSE:	

101	How would you describe your overall satisfaction with your TOP?	Very satisfied,……1 Somewhat satisfied……..2 Neutral……3 Somewhat dissatisfied……..4 Very dissatisfied……..5	
102	Would you recommend the TOP method you just experienced to a friend who needed a TOP at your stage of pregnancy?	Yes, highly agree,……1 Yes, somewhat agree……..2 Neutral……..3 No Somewhat disagree……..4 No, highly disagree……..5	
103	If you needed a TOP yourself at this stage of pregnancy in the future, would you want to have this same procedure again?	Yes, highly agree,……1 Yes, somewhat agree……..2 Neutral……..3 No Somewhat disagree……..4 No, highly disagree ……..5	
104	How would you describe your overall physical pain or discomfort with your TOP from start to finish?	None……..1 Slight……..2 Moderate……3 High……4 Extreme……..5	
	c) Were you given pain medicine to use if needed, from the time you were admitted until you completed the TOP?	Yes…..1 / No….2 / Don't know……9	
	d) if Yes: Did you feel better after you took it	Not at all……..1 Somewhat……2 Very Much……3	
105	How would you describe your emotional discomfort with your TOP?	None……..1 Slight……..2 Moderate……3 High……4 Extreme……..5	
	IF MODERATE, HIGH OR EXTREME EMOTIONAL DISCOMFORT a) Why do you say that you had [moderate / high/ extreme] emotional discomfort with your TOP?	OPEN RESPONSE:	
107aN	On what date and at what time did you take the first abortion pill? INTERVIEWER SHOW PATIENT A MIFE TABLET Where did you take the first abortion pill?	Date: ___/ ___/ _____ Time: _____ (HH / MM) Home……..1 Hospital …… 2 Other …… 3 Other (specify) _____	
107	a. During your TOP, did you realise the fetus had come out (of your vagina)?	Yes……1 / No…..2 / Don't know…..9	

	b. Where did that happen?	At home……1 In the transport to the hospital……2 In the hospital waiting room……3 In the hospital bed……4 In the toilet at the hospital……5 Other ……6 Other (specify) _____	
	c. And how did you feel when you noticed the fetus had come out? Interviewers: Do NOT prompt CIRCLE "Yes" if mentioned "No" if not mentioned		
	Shocked	Yes……1 / No…..2	
	Scared/fearful	Yes……1 / No…..2	
	Relief	Yes……1 / No…..2	
	Sad/ bad/ hurt /emotional	Yes……1 / No…..2	
	Pain/ physical symptoms	Yes……1 / No…..2	
	Guilty/ regretful/ bitter	Yes……1 / No…..2	
	Traumatized	Yes……1 / No…..2	
	Numb /no feelings or reaction	Yes……1 / No…..2	
	Other	Yes……1 / No…..2	
	Other (specify)	_____	
108	At any time since starting the TOP (including when you took the first medication did you have any of the following problems?		
	a) Vomiting	Yes……1 / No…..2 / Don't know…..9	
	b) Dizziness	Yes……1 / No…..2 / Don't know…..9	
	c) Tiredness	Yes……1 / No…..2 / Don't know…..9	
	d) Pain in your lower abdomen	Yes……1 / No…..2 / Don't know…..9	
	e) Breast tenderness	Yes……1 / No…..2 / Don't know…..9	
	f) Headache	Yes……1 / No…..2 / Don't know…..9	
	g) Nausea	Yes……1 / No…..2 / Don't know…..9	
	h) Diarrhea	Yes……1 / No…..2 / Don't know…..9	
	i) Cold	Yes……1 / No…..2 / Don't know…..9	
	j) Heat/sweating	Yes……1 / No…..2 / Don't know…..9	
	k) Other symptoms	Yes……1 / No…..2 / Don't know…..9	

	l) If Other: describe	[Open response]	

TOP Section 2: Care seeking experiences leading to procedure

NO.	QUESTIONS	CODING CLASSIFCATION	
200NEW 200a	Including this hospital, how many different clinics or hospitals have you been to relating to this TOP? Total number of visits at ALL Facilities	NUMBER OF FACILITIES_____ NUMBER OF VISITS_____	
	FIRST CLINIC		
201	Try to remember the first clinic or hospital you went to when you decided to get the TOP. Was it this facility? Interviewers: First list facility names and dates for all visits on your Notes page. IF: SHIPLEY then SOMERSET next : SKIP TO QUESTION 219 IF GSH OPD then GROOTE SCHUUR: SKIP TO QUESTION 219 IF TC NEWMAN then PAARL next: SKIP TO QUESTION 219	Yes……1 / No…..2 / Don't know…..9	
	b) What was the name of the place that you went first?	[Write name of place and code] NAME_____ CODE_____ Don't know ……..999	
202	When did you first go there to try to get this TOP? Interviewer: Work out when she became pregnant. Use calendar to determine date. If no day, use 15.	Date: _____ _____ _____ dd / mm / yy Don't know…99 /99/ 99	
202NEW	What service did you receive at this facility?		
	a) Pregnancy test	Yes……1 / No…..2 / Don't know…..9	
	b) TOP counselling	Yes……1 / No…..2 / Don't know…..9	
	c) Sonar to find out how many weeks the pregnancy is	Yes……1 / No…..2 / Don't know…..9	
	d) referral to TOP facility	Yes……1 / No…..2 / Don't know…..9	
	e) booking for TOP	Yes……1 / No…..2 / Don't know…..9	
	f) Information about what the TOP will involve	Yes……1 / No…..2 / Don't know…..9	

NO.	QUESTIONS	CODING CLASSIFCATION	
203NEW	a) Did you visit this facility more than once? b) On what date was this visit? c) What Service did you receive at this visit? Code: Ultrasound US Counselling CO Referral letter RL Other O Interviewer: If client visited this facility more than twice – please obtain as much detail as possible about each subsequent visit at this facility.	Yes……1 / No…..2 Date: _____ _____ _____ dd / mm / yy CODE_____ Other (specify) _____ OPEN RESPONSE:	
207	a) Were you then referred somewhere else?	Yes……1 / No…..2 / Don't know…..9	
	b) If Yes: Name referral site:	[Write name of place and code] NAME_____ CODE_____ Don't know ……..999	
	c) If No: what did you do then	OPEN RESPONSE	
	SECOND CLINIC		
208	What clinic or hospital did you go to next? IF Shipley then Somerset next : SKIP TO QUESTION 219 IF GSH OPD then GROOTE SCHUUR: SKIP TO QUESTION 219 IF TC NEWMAN then PAARL next: SKIP TO QUESTION 219	[Write name of place and code] NAME_____ CODE_____ Don't know ……..999	
209	When did you first go there to try to get this TOP? Interviewer: Use calendar to determine date	Date: _____ _____ _____ dd / mm / yy Don't know…99 / 99 / 99	
209NEW	What service did you receive at this facility?		
	a) Pregnancy test	Yes……1 / No…..2 / Don't know…..9	
	b) TOP counselling	Yes……1 / No…..2 / Don't know…..9	
	c) Sonar to find out how many weeks pregnancy is	Yes……1 / No…..2 / Don't know……9	
	d) referral to TOP facility	Yes…….1 / No…..2 / Don't know……9	
	e) booking for TOP	Yes……1 / No…..2 / Don't know….. 9	

NO.	QUESTIONS	CODING CLASSIFCATION	
210NEW	a) Did you visit this facility more than once? b) On what date was this visit? c) What Service did you receive at this visit? Code: Ultrasound US Counselling CO Referral letter RL Other O Interviewer: If client visited this facility more than twice – please obtain as much detail as possible about each subsequent visit at this facility.	Yes……1 / No…..2 Date: _____ _____ _____ dd / mm / yy CODE_____ Other (specify) _____ OPEN RESPONSE:	
216	a) Were you then referred <u>somewhere else?</u>	Yes……1 / No…..2 / Don't know…… 9	
	b) If yes: Name referral site:	[Write name of place and code] NAME_____ CODE_____ Don't know ……..999	
	c) If No: what did you do then	OPEN RESPONSE	
	OTHER CLINICS		
217	Did you go to any other clinics or hospitals before coming here to this hospital?	Yes……1 / No…..2 / Don't know…..9	
218NEW	Besides the places you just mentioned and this hospital, which other clinics or hospitals did you go to before coming here and what service did you receive there?	Name_____ Code _____ Don't know ……..999 Service_____	

NO.	QUESTIONS	CODING CLASSIFCATION	
		Name_____ Code_____ Don't know ……..999 Service_____	
	HOSPITAL WHERE PROCEDURE TOOK PLACE		
219	Now I would like you to think about when you came to this hospital for this TOP. When did you come here for this TOP? Probe: check q202 that q219 is not prior to that date The outpatient facility at the hospital is included here as this facility: Shipley = Somerset GSH OPD = GSH TC NEWMAN = PAARL	Date: _____ _____ _____ dd / mm / yy Don't know…99 / 99 / 99	
219N	What time did you arrive at this hospital on the day you were admitted to the ward?	Time: _____ (HH / MM)	
220	Including today, how many visits to this hospital have you had related to this TOP?	Number of visits_____	
220v1	What service did you receive at your <u>first visit</u> to this facility?		
	a) Pregnancy test	Yes……1 / No…..2 / Don't know…..9	
	b) TOP counselling	Yes……1 / No…..2 / Don't know…..9	
	c) Sonar to find out how many weeks the pregnancy is	Yes……1 / No…..2 / Don't know…..9	
	d) referral to TOP facility	Yes……1 / No…..2 / Don't know…..9	
	e) booking for TOP	Yes……1 / No…..2 / Don't know…..9	
	g) Mifepristone (abortion pill)	Yes……1 / No…..2 / Don't know…..9	
220v2	What service did you receive at your second visit to this facility?		
	a) Pregnancy test	Yes……1 / No…..2 / Don't know…..9	
	b) TOP counselling	Yes……1 / No…..2 / Don't know…..9	
	c) Sonar to find out how many weeks the pregnancy is	Yes……1 / No…..2 / Don't know…..9	
	d) referral to TOP facility	Yes……1 / No…..2 / Don't know…..9	
	e) booking for TOP	Yes……1 / No…..2 / Don't know…..9	
	g) Mifepristone (abortion pill)	Yes……1 / No…..2 / Don't know…..9	
220v3	What service did you receive at your third visit to this facility?		
	a) Pregnancy test	Yes……1 / No…..2 / Don't know…..9	
	b) TOP counselling	Yes……1 / No…..2 / Don't know…..9	
	c) Sonar to find out how many weeks the pregnancy is	Yes……1 / No…..2 / Don't know…..9	
	d) referral to TOP facility	Yes……1 / No…..2 / Don't know…..9	

NO.	QUESTIONS	CODING CLASSIFCATION	
	e) booking for TOP	Yes……1 / No…..2 / Don't know…..9	
	g) Mifepristone (abortion pill)	Yes……1 / No…..2 / Don't know…..9	
220VF	What service did you receive at this visit?		
	a) Pregnancy test	Yes……1 / No…..2 / Don't know…..9	
	b) TOP counselling	Yes……1 / No…..2 / Don't know…..9	
	c) Sonar to find out how many weeks the pregnancy is	Yes……1 / No…..2 / Don't know…..9	
	d) referral to TOP facility	Yes……1 / No…..2 / Don't know…..9	
	e) booking for TOP	Yes……1 / No…..2 / Don't know…..9	
	f) TOP	Yes……1 / No…..2 / Don't know…..9	
223	From the time when you first came here to when you were admitted for the TOP procedure. Did the staff at this facility tell you anything about the abortion procedure	Yes……1 / No…..2 / Don't know…..9	
224	What type of information did they tell you about the abortion?		
	a) Where you would have procedure	Yes……1 / No…..2 / Don't know…..9	
	b) When you would have procedure	Yes……1 / No…..2 / Don't know…..9	
	c) How long procedure would take	Yes……1 / No…..2 / Don't know…..9	
	d) Information about taking medications before procedure	Yes……1 / No…..2 / Don't know…..9	
	e) Amount of pain you would have with procedure	Yes……1 / No…..2 / Don't know…..9	
	f) What the recovery would be like after procedure	Yes……1 / No…..2 / Don't know…..9	
	g) Information about contraception after procedure	Yes……1 / No…..2 / Don't know…..9	
	h) Other: describe:	[Open response]	
225	At this facility who talked to you about the abortion <u>before</u> you were admitted in the ward?		
	a) Doctor	Yes……1 / No…..2 / Don't know…..9	
	b) Nurse	Yes……1 / No…..2 / Don't know…..9	
	c) Other staff	Yes……1 / No…..2 / Don't know…..9	
	d) If Yes: List	_____	
	We know that some women in South Africa try to do TOP at home using herbs or tablets or drinking special mixes. Some women also try to do it outside of a clinic or hospital by calling special phone numbers that advertise TOP.		
227	a) Before you had this TOP here in the hospital, did you try any other methods to end the pregnancy	Yes……1 / No…..2 / No response…..9	

NO.	QUESTIONS	CODING CLASSIFCATION	
	b) IF YES, what did you try?	OPEN RESPONSE	
	c) IF YES, where did you do this?	OPEN RESPONSE	

NO.	QUESTIONS	CODING CLASSIFCATION	
303	***During*** the TOP procedure, when you were here in the ward, did the doctor or nurse talk with you?	Yes…..1 / No…..2 / Don't know…..9	
	If Yes: did s/he talk about		
	a) Info about how procedure is going	Yes…..1 / No…..2 / Don't know…..9	
	b) Offer pain medication	Yes…..1 / No…..2 / Don't know…..9	
	c) Offer sympathetic support	Yes…..1 / No…..2 / Don't know…..9	
	d) Other	OPEN RESPONSE	
304	How satisfied did you feel with the ***emotional support*** you received from the doctor or nurse during the TOP procedure?	Very satisfied,……1 Somewhat satisfied……..2 Neutral……3 Somewhat dissatisfied…….4 Very dissatisfied……..5	

NO.	QUESTIONS	CODING CLASSIFCATION	SKIP TO
401NEW	Since the TOP procedure ended has the doctor or nurse or someone else from the hospital spoken with you or given you information (oral or written)?	Yes……1 / No…..2 / Don't know…..9	
402	What did you get information about?		
	a) How the procedure went	Yes……1 / No…..2 / Don't know…..9	
	b) Any symptoms that may occur which are not normal	Yes……1 / No…..2 / Don't know…..9	

NO.	QUESTIONS	CODING CLASSIFCATION	SKIP TO
	c) Amount of pain you would have after procedure	Yes……1 / No…..2 / Don't know…..9	
	d) Other side effects after procedure	Yes……1 / No…..2 / Don't know…..9	
	e) What the recovery would be like after procedure	Yes……1 / No…..2 / Don't know…..9	
	f) Information about contraception after procedure	Yes……1 / No…..2 / Don't know…..9	
	g) Where you can go if you have a problem	Yes……1 / No…..2 / Don't know…..9	
	h) Other: describe	[Open Response]	
FAMILY PLANNING (FP) : INTERVIEWERS ASK CLIENT: PLEASE CAN YOU TELL ME AGAIN: DID ANYBODY AT THIS FACILITY (or here in the OPD) SPEAK TO YOU ABOUT FAMILY PLANNING : IF CLIENT ANSWERS " NO", skip to 406:			
FP1	I'd like to know what the nurse/doctor/ social worker told you about family planning. Did s/he tell you about different kinds of family planning methods?	Yes……1 / No…..2 / Don't know…..9	
FP2	IF YES, what kinds of methods did s/he tell you about? **[PROBE regarding permanent methods, partner methods, etc.]**		
	a) Abstinence	Yes……1 / No…..2 / Don't know…..9	
	b) Female sterilization: tying of tubes	Yes……1 / No…..2 / Don't know…..9	
	c) Male sterilization: vasectomy	Yes……1 / No…..2 / Don't know…..9	
	d) IUD/loop/copper T	Yes……1 / No…..2 / Don't know…..9	
	e) Injection	Yes……1 / No…..2 / Don't know…..9	
	f) Pills	Yes……1 / No…..2 / Don't know…..9	
	g) Male condoms	Yes……1 / No…..2 / Don't know…..9	
	h) Emergency contraception	Yes……1 / No…..2 / Don't know…..9	
	i) Female condoms	Yes……1 / No…..2 / Don't know…..9	
	j) Other methods	Yes……1 / No…..2 / Don't know…..9	

NO.	QUESTIONS	CODING CLASSIFCATION	SKIP TO
	k) Other (Specify)	_____ ___	
FP3	Did you receive information on how the method(s) work(s) in your body to prevent pregnancy?	Yes……1 / No…..2 / Don't know…..9	
FP4	Did you receive information on the side effects that the method(s) might cause?	Yes……1 / No…..2 / Don't know…..9	
FP5	Did you receive information on how often you need to go to get more of the method(s)?	Yes……1 / No…..2 / Don't know…..9	
NB DATA ENTRY: BACK TO PREVIOUS NUMBERING SYSTEM			
406	Do you plan to start a family planning method after the TOP?	Yes……1 / No…..2 / Don't know…..9	
407	Why don't you plan to use a family planning method?	_____ ___	
408	What family planning method do you plan to use?	_____ ___	
409	a) Did / Will you receive a family planning method before leaving this facility?	Yes……1 / No…..2 / Don't know…..9	I
	b) What family planning method did / will you receive before leaving this facility?	_____	
	c) Do you know **when** you need to renew/get more of that method?	Yes……1 / No…..2 / Don't know…..9	
	d) Do you know **where** to go so that you can get more of it?	Yes……1 / No…..2 / Don't know…..9	
	k) Other (Specify)	_____ ___	
413	After you go home today, where would you go if you had a medical problem related to the TOP		
	a) This hospital	Yes……1 / No…..2 / Don't know…..9	
	b) Other hospital or clinic If Yes: list	Yes……1 / No…..2 / Don't know…..9 _____	

NO.	QUESTIONS	CODING CLASSIFCATION	SKIP TO
	c) Private doctor	Yes…...1 / No…..2 / Don't know…..9	
	d) Other health facility If Yes: List	Yes…...1 / No…..2 / Don't know…..9 _____	
	e) Other practitioner	Yes…..1 / No….2 / Don't know…..9	
416	a) When a woman falls pregnant, there has been unprotected sex. In South Africa, we know that HIV is a big concern for many people, and having unprotected sex puts a person at risk of HIV-infection. b) Have you ever tested for HIV? If yes, you don't need to tell me the result. I just want to know if you have ever tested.	Yes…..1 / No…..2 / No response....9	
	b) Do you think it would be good if the doctor or nurse who helps women with TOPs asked each woman if she would like to have an HIV test?	Yes…..1 / No…..2 / Don't know…..9	
	c) If someone had asked you during your TOP if you wanted to test for HIV, would you have said yes? I'm asking this so that in the future, we will know what women want. I'm not offering HIV tests today but I can tell you where HIV testing is done if you would like	Yes…..1 / No…..2 / Don't know…..9	
Thank you very much for your participation in this research.			
Interviewer comments and observations:			

Procedure Form

NO.	QUESTIONS	CODING CLASSIFCATION	
	Date of admission		
A	Approximate time of admission		
	Date of discharge (Doctor's sign off)		
A	Approximate time of discharge (Doctor's sign off)		
	Age		
	Parity		
	Gestational age by ultrasound	_____WEEKS_____DAYS	
	Date ultrasound was performed	_____/_____/_____	
109A	Time of expulsion of fetus	DATE_____ TIME_____ NOT EXPELLED SPONTANEOUSLY 99	
	Time of expulsion of placenta	DATE_____ TIME_____ NOT EXPELLED SPONTANEOUSLY 99	
	Was surgical procedure performed?	CURETTAGE ... 1 SUCTION ASPIRATION 2 LAPAROTOMY 3 OTHER_____ 4 NO SURGICAL PROCEDURE 5	
110A	Was fetal or placental tissue removed from the cervix by hand or using an instrument?	OVUM FORCEPS……1 MANUAL…….. 2 OTHER_____ __-…….3 NOT RECORDED…….. 4	
	Date/time of surgical procedure	DATE_____ ___ TIME_____ ____	
	Anesthesia used during surgical procedure CIRCLE ALL THAT APPLY	PARACERVICAL BLOCK 1 CONSCIOUS SEDATION 2 GENERAL ANESTHESIA 3 OTHER_____ 4 NO ANESTHESIA 5	
	Reason for surgical procedure	INDUCTION FAILURE (FETUS DID NOT EXPEL)……. ……..1 RETAINED PLACENTA……..2 HEAVY BLEEDING……..3 ROUTINE CURETTAGE, OR NO REASON SPECIFIED……4 NOTES:	

NO.	QUESTIONS	CODING CLASSIFCATION	
113aN	Mifepristone	DATE_____(ACTUAL) TIME _____(ACTUAL)	
	1st dose of misoprostol	DATE_____TIME_____h____ DOSAGE:_____mcg ROUTE (circle): PO Buccal SL PV	
	2nd dose of misoprostol	DATE_____TIME_____h____ DOSAGE :_____mcg ROUTE (circle): PO Buccal SL PV	
	3rd dose of misoprostol	DATE_____TIME_____h____ DOSAGE:_____mcg ROUTE (circle): PO Buccal SL PV	
	4th dose of misoprostol	DATE_____TIME_____h____ DOSAGE:_____mcg ROUTE (circle): PO Buccal SL PV	
	5th dose of misoprostol	DATE_____TIME_____h____ DOSAGE:_____mcg ROUTE (circle): PO Buccal SL PV	
	6th dose of misoprostol	DATE_____TIME____h____ DOSAGE:_____mcg ROUTE (circle): PO Buccal SL PV	
	7th dose of misoprostol	DATE_____TIME_____h____ DOSAGE:_____mcg ROUTE (circle): PO Buccal SL PV	
	8th dose of misoprostol	DATE_____TIME_____h____ DOSAGE:_____mcg ROUTE (circle): PO Buccal SL PV	
	9th dose of misoprostol	DATE_____TIME_____h____ DOSAGE:_____ ROUTE (circle): PO Buccal SL PV	
	10th dose of misoprostol	DATE_____TIME_____h____ DOSAGE:_____mcg ROUTE (circle): PO Buccal SL PV	
123A	IF more than 10 doses of Misoprostol, note total OR circle 99 if <=10 doses	TOTAL NO of Miso doses _____ NOT MORE THAN 10 DOSES GIVEN ..99	
124	If other priming agent(s) (like laminaria) used, note time, dose/number OR circle 99 if NONE given	DATE_____TIME_____h____ AGENT_____ DOSE/NUMBER_____ NOT GIVEN 99	
125	Medication name (Circle correct answer) Syntocinon/Pitocin/Oxytocin/Other (please write) ……	DATE_____TIME_____h____ DOSE_____ IU _____ ROUTE (circle): PO IV IM PV NOT GIVEN 99	
126	Family Planning (Circle correct answer) Depo /Neten/ IUD/ Oral / Other (please write) …….	DATE: On Admission/ Interim/ Discharge ROUTE (circle): PO IV IM PV IU NOT GIVEN 99	

NO.	QUESTIONS	CODING CLASSIFCATION	
127	1st Antibiotic (If Flagyl/Metronidazle & Doxycycline & Cefixime, write Flagyl/Metranidazole first, then Doxy, then Cefixime in 132a) Name_____	 DATE: On Admission/ Interim/ Discharge DOSE_____ ROUTE (circle): PO IV IM PV NOT GIVEN 99	
128	2nd Antibiotic Name_____	DATE: On Admission/ Interim/ Discharge DOSE_____ ROUTE (circle): PO IV IM PV NOT GIVEN 99	
129	Analgesia Name_____	DATE: On Admission/ Interim/ Discharge DOSE_____ ROUTE (circle): PO IV IM PV NOT GIVEN 99	
131	Blood/packed cells transfusion	DATE_____ TIME_____ DOSE_____ NOT GIVEN 99	
132	Other Medications; List Names	 Name a)_____ Name b)_____ Name c)_____ Name d)_____	
130	In case of any complication, select complication from list (or describe) and note details ANY Complications……..Y=1 / No 0 a. Suspected uterine rupture……Y=1 / No 0 b. Suspected uterine perforation at time of curettage……..Y=1 / No 0 c. Seizure……Y=1 / No 0 d. Hemorrhage requiring transfusion (according to physician)…….Y=1 / No 0 e. Hemorrhage not requiring transfusion (estimated blood loss >500 mL)…….Y=1 / No 0 f. Trauma to cervix or vagina requiring surgical repair……..Y=1 / No 0 g. Transfer to another facility to complete the procedure……Y=1 / No 0 h Other:_____..... …Y=1 / No 0 Details:		